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Health Law Journal

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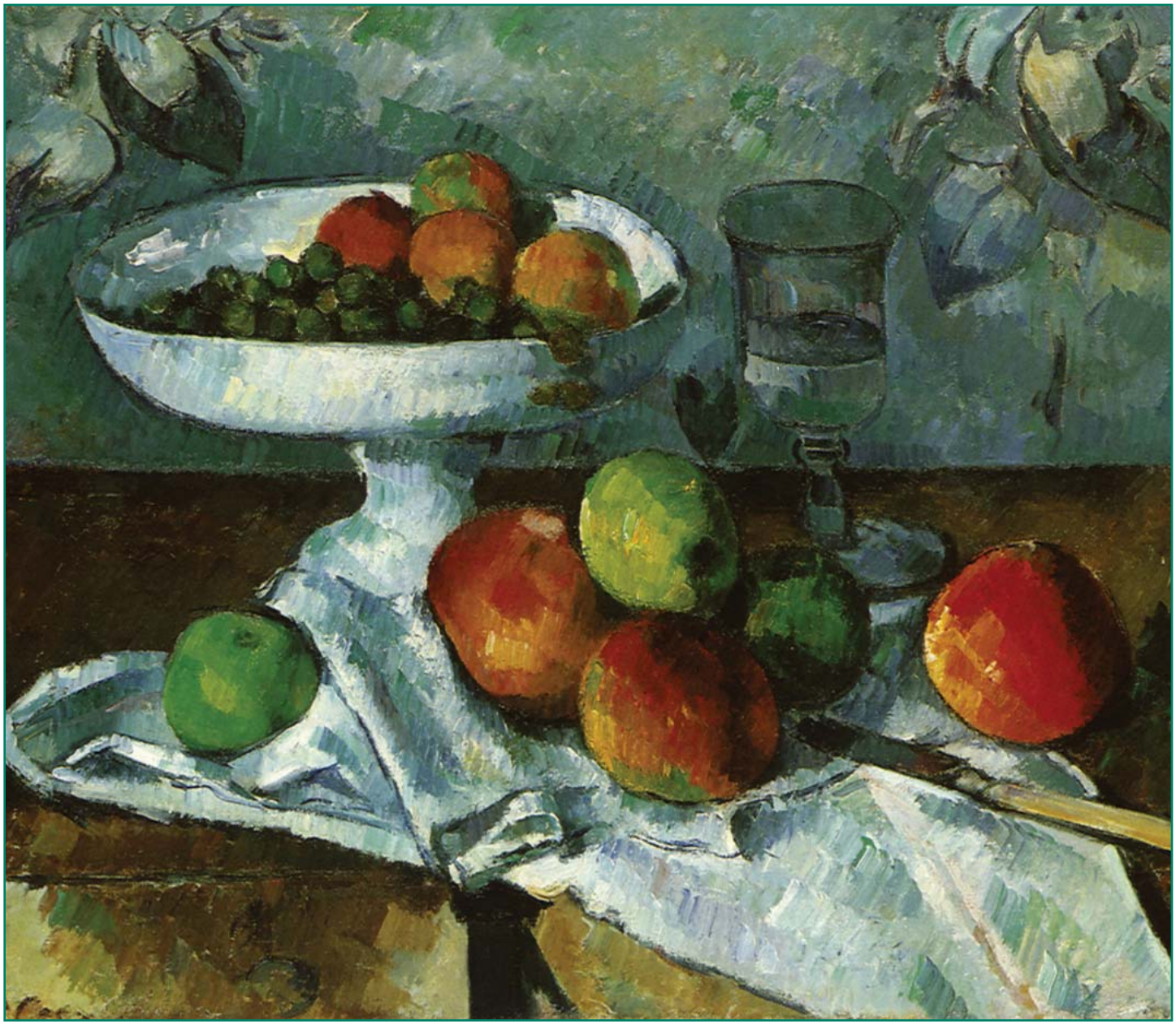

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork:
***Still Life* by Paul Cézanne (1880)**

A Message from the Chair

We have finally seen the adoption of near universal health insurance in the United States. Yet, even as we contemplate the vast implications, we realize that the deferred implementation dates of many of the critical provisions (individual mandate, Cadillac tax) will allow for repeal efforts. Perhaps ultimately, Obama's re-election will determine the fate of reform.

The effects of reform will be very broad, affecting every American, e.g., insurance coverage or expanded Medicaid for everyone; increased taxes for the wealthy, insurance companies and pharmaceutical device companies; and provider payment and Medicaid advantage cuts. But perhaps the greatest near-term impact (other than on the 30 million Americans who now have insurance) will be the impact on employer health plans. Will the existing employer-based health model survive the development of the insurance exchanges coming in 2014? Will employers opt out of providing health care? In this regard, reform has eliminated the tax deductibility of the subsidy that had been provided since the adoption of the Medicare Prescription Drug Benefit to plans that maintained their prescription drug programs for retirees. This resulted in a substantial charge to earnings by a number of public companies that has been somewhat controversial. It is expected, however, that many employers may now terminate their retiree health benefit plans, which will force the retirees on to the Medicare patient public benefit. Later, once the employer coverage obligations kick in (2014), many employers may decide to pay the penalty for having employees in the exchanges, and eliminate their employment-based coverage. These employees would then be covered through the exchanges and presumably, the employer will increase wages to subsidize the purchase of insurance through the exchanges by employees.

If the foregoing scenario plays out on a large scale, the Health Care Reform Bill may be the beginning of the end of employer-sponsored insurance as the dominant non-public source of coverage.

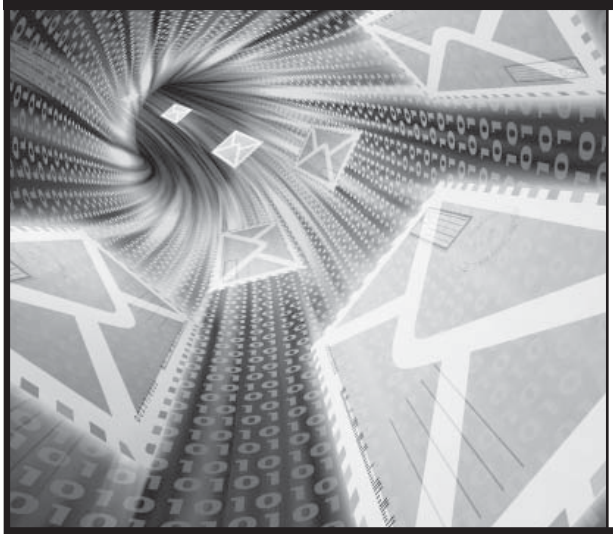
Another key question is whether Reform's version of integrated care, the "accountable care organization" made up of providers that service all of an insured's needs, will fare better than prior efforts at health maintenance organizations and achieve what they had not in lower costs and improved quality.

It is once again a time of change in health care. In my more than 30 years practicing health care law, that has always been true, just sometimes more true than others. We look forward to thousands of pages of regulatory guidance, legal challenges, and much uncertainty. We are health care lawyers.

Ed Kornreich

Note: On June 1, 2010, Ari Markenson became Chair of the Health Law Section.

Request for Articles



If you have written an article you would like considered for publication, or have an idea for one, please contact the *Health Law Journal* Editor:

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In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Affirms That Mental Hygiene Legal Services Does Not Have Jurisdiction Over Nursing Home Residents With Mental Disabilities

Hirschfeld v. Teller, __N.E.2d __, 2010 WL 1194174 (N.Y. March 30, 2010). In this suit, the director of Mental Hygiene Legal Services ("MHLS") sought a judgment declaring that MHLS has a right of access to mentally disabled nursing home residents.

MHLS sought access to residents admitted to segregated units of nursing homes, known as "neurobiological units" ("NBU units"), after being discharged from facilities licensed by the Office of Mental Health ("OMH"). MHLS sought such access to provide advocacy and legal representation after an investigation suggested that such residents were deprived of the legal protections afforded to similarly situated patients in the psychiatric wards of hospitals.

The nursing homes argued that MHLS had no right to access to the residents because the Mental Hygiene Law provides MHLS with jurisdiction only over facilities required to obtain operating certificates from OMH and, according OMH, nursing homes are not required to have OMH operating certificates.

The Court of Appeals affirmed denial of the relief sought. The Court found that under the Mental Hygiene Law, MHLS's jurisdiction was limited to two categories of facilities. MHLS asserted that the nursing homes fell under one of these categories—namely, places that are required to have an OMH operating certificate. Further, MHLS argued that the key factor is whether facilities are subject to licensing because they provide residential services to patients with mental disabilities.

The Court stated that which facilities are subject to OMH licensure is wholly within OMH's discretion and expertise. Because OMH exercised its authority and decided that the nursing homes did not require licensure and an operating certificate, MHLS had no jurisdiction over such facilities. In so finding, the Court noted that it was making no determination as to OMH's underlying licensure decision, and that any challenges to such decision must be brought through an Article 78 proceeding.

In a dissenting opinion, Chief Judge Lippman found that the Mental Hygiene Law had been amended in 1993 for the purpose of extending MHLS's jurisdiction to cover patients with mental disabilities at residential facilities such as the nursing homes here. The legislative history surrounding the amendment indicates that the legislature intended that MHLS have full access to represent patients with mental disabilities without first having to establish jurisdiction.

The dissent noted that the majority's interpretation of the Mental Hygiene Law establishing MHLS's limited jurisdiction was "textually incorrect and plainly at odds with the purposes informing its enactment." It had become common practice for state psychiatric hospitals to discharge patients to NBU units where they continued to receive psychiatric treatment in "highly restrictive settings"—virtually the same as involuntary psychiatric care—without any protection of the patients' due process rights, which they had been afforded while involuntarily committed to OMH licensed facilities. Chief Judge Lippman wrote that the majority's narrow reading of the Mental Hygiene Law so as to limit MHLS's jurisdiction may have a devastating impact on the rights and liberty interests of a needy population.

Chief Judge Lippman also argued against the majority's rationale that MHLS's jurisdiction is dependent upon OMH's administrative decision as to whether a facility is required to obtain an operating certificate. He noted that, pursuant to the Mental Hygiene Law, an OMH operating certificate is required for a residential facility providing care or treatment of the mentally disabled and that, although nursing homes traditionally did not provide such care, the fact that the nursing homes here were essentially providing involuntary inpatient care to the mentally disabled, there would be no grounds to find that such nursing homes were not subject to OMH licensure, and that such determination should be made by the courts, not by OMH.

Federal District Court Denies Parents' Motion for Preliminary Injunction to Compel School to Register Unvaccinated Child

Cavaziel v. Great Neck Public Schools., et al., 2010 WL 1269696 (E.D.N.Y. Apr. 5, 2010). Parents of a child just under four years old alleged that their school district violated their state and federal constitutional rights, based on the denial of their application for an exemption from vaccinating their child prior to enrollment in the district's pre-kindergarten program. The Plaintiffs also moved for a preliminary injunction seeking to compel the school district to register their unvaccinated child based on the religious belief exemption. After denying the Plaintiffs' motion for a temporary restraining order, the Court held a hearing on the preliminary injunction motion.

New York State Public Health Law § 2164(7) requires children entering public school to be vaccinated against certain diseases. However, Plaintiffs argued that they are entitled to the exemption to this rule, as provided by Subdivision 9: the rule shall not apply to "children whose… parents…hold genuine and sincere religious beliefs which are contrary to the practices herein required.…"

After disposing of peripheral issues relating to notice of claim and exhaustion, the Court focused on whether Plaintiffs met the heightened standard for a preliminary injunction that affects government action taken in the public interest pursuant to a statutory or regulatory scheme. This more rigorous standard requires that the injunction be granted only if the moving party shows both (1) irreparable harm and (2) a likelihood of success on the merits. The Court concluded that the Plaintiffs satisfied the first prong by showing there would be irreparable harm to their child if she was unable to enter school in September 2010.

As to the second prong, the Court considered the Plaintiffs' argument that they are entitled to the religious belief exemption to the vaccination rule by the New York Public Health Law, as well as the First and Sixth Amendments, because of their "genuine and sincere religious beliefs." The Court concluded that the Plaintiffs' objections, although sincere, were not religious in nature and are thus not entitled to the exemption. Although the law does not require the Plaintiffs to be a member of an organized religion, Mrs. Cavaziel is a member of the Sanctuary of the Beloved Church, which does not express opposition to vaccination, according to her testimony at the hearing. Furthermore, Mrs. Cavaziel revealed that her beliefs are personal, and not religious, through numerous examples in her testimony. Specifically, she described her concern that vaccinations cause autism, which concern has no ties to any religious beliefs. She also admitted that she takes Motrin and essential oils despite her religion's belief that the body is divine and needs no medications.

Furthermore, in a letter drafted by Plaintiffs' attorney regarding the family's religious beliefs, the Court found the following language revealing: "For thousands of years our ancestors never injected diseases into their bodies, nor do we want to now inject diseases or make unnecessary marks on our bodies." Believing that there is nothing religious about this statement, the Court concluded that it simply shows personal feelings relating to a fear of injecting disease into the body and a reluctance to make unnecessary bodily marks. Mrs. Cavaziel had no such feelings when she vaccinated her three older children, and when she pierced her own ears, and those of her daughter. Because such feelings are more in the nature of a secular philosophy than a religious belief, the Court concluded that Plaintiffs are unlikely to succeed on their claim that they qualify for the religious belief exemption to the vaccination requirement and denied Plaintiffs' preliminary injunction motion accordingly.

False Claims Act Suit Based on Allegations of Care Provided by Unsupervised Medical Residents Dismissed for Failure to Plead That Claims for Payment Were Submitted to the Government

Johnson v. University of Rochester Medical Center, 2010 WL 598655 (W.D.N.Y. Feb. 18, 2010). Plaintiffs, a physician and a registered nurse, brought a *qui tam* action against their former employers alleging, *inter alia*, violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* ("FCA").

The *qui tam* provisions of the FCA encourage private citizens to come forward with information regarding acts of fraud against the U. S. government by permitting such Plaintiffs to share in the resulting recovery. Plaintiffs in this action alleged that the defendants had defrauded the U.S. government by filing false claims for payment under New York Medicare/Medicaid and other Federal programs. Specifically, Plaintiffs alleged that defendants had fraudulently billed the government for procedures performed by residents without the required presence or supervision of a teaching or attending physician, in violation of relevant Medicare/Medicaid regulations. Further, Plaintiffs alleged that they had been retaliated against for refusing to alter medical records to falsely reflect the attendance of physicians during such procedures, and for reporting to supervisors that medical records had been altered in this manner to obtain reimbursement.

The court noted that Plaintiffs' complaint included lengthy allegations of defendants' repeated failure to provide the supervision of residents by teaching/attending physicians as required, as well as multiple allegations concerning falsified information on patient records. Nevertheless, the court dismissed Plaintiffs' fraud claims for failing to allege that bills for any of the described procedures were ever presented to the government for payment. In so ruling, the court instructed that the FCA attaches liability not to the underlying fraudulent activity, but to the claim for payment from the government. Thus, the "central question under the False Claims Act is whether the defendant actually presented a 'false or fraudulent claim' to the government."

Plaintiffs argued that they were unable to make such allegations because evidence of defendants' Medicare/Medicaid reimbursement requests was in the sole possession of the defendants. The court was not persuaded, holding that although fraud can be pleaded on information and belief where the defendant has exclusive control over relevant evidence, a Plaintiff must still set forth the factual basis for such belief, and that basis must arise from the Plaintiff's direct, independent, firsthand knowledge. Because Plaintiffs had

failed to identify or describe any particular false claims that were presented to the government for payment, their fraud claims were dismissed for failure to satisfy the particularity requirement of Federal Rule of Civil Procedure 9(b).

Plaintiffs' claims under the FCA for retaliatory discharge were similarly dismissed for failure to allege termination in retaliation for an investigation, inquiry or testimony directed at exposing a fraud on the government. The court held that Plaintiffs' actions, as described in their pleadings, were motivated by frustration at physicians who were ignoring their responsibility to supervise residents, at the peril of the residents and their patients, and by moral objections to falsifying records, rather than by a desire to expose a fraud on the government. While noting that such motives are commendable, the court held them insufficient to bring Plaintiffs' allegations within the FCA.

Excluded Medicaid Provider Properly Terminated Under Employment Agreement with Hospital Where Services May Have Violated Medicaid Regulations

William J. DeTorres III, M.D., P.C. v. Claxton-Hepburn Medical Center, 65 A.D.3d 733, 883 N.Y.S.2d 659 (3d Dep't 2009). Claxton-Hepburn Medical Center (the "Medical Center") entered into a Hospitalist Physician Services Agreement (the "Agreement") with Plaintiff William J. DeTorres III, M.D., P.C. The Agreement required Dr. DeTorres to provide emergency medical services to patients who did not have an assigned physician or whose attending physicians were unavailable. The Agreement did not require Plaintiff to be a Medicaid provider, and the Medical Center was aware that Dr. DeTorres was excluded from participation in the Medicaid program.

After hiring Plaintiff, the Medical Center received a Medicaid publication which strongly advised against hiring excluded Medicaid providers. The Medical Center thereafter invoked a provision in the Agreement that permits termination of the Agreement "without liability, if on the advice of its counsel it determines in its reasonable judgment that the terms of the Agreement more likely than not may be interpreted to violate any present or proposed future law or regulation."

Plaintiff sued the Medical Center for breach of the Agreement, among other claims. The Appellate Division affirmed dismissal of the complaint. The court found that the Medicaid publication and a Medicaid regulation imposing sanctions against a provider for any involvement by an excluded person in the care of a Medicaid patient (*see* 18 NYCRR 515.5) constituted good cause for the Medical Center's counsel to determine, based upon its reasonable judgment, that the Agreement could be interpreted to violate a law or regulation.

In its finding for the Medical Center, the Court noted that, although the Agreement did not expressly require Plaintiff to provide medical treatment to Medicaid patients, and that the Medical Center could possibly have avoided a penalty by having Plaintiff serve only non-Medicaid patients, the Agreement clearly obligated Plaintiff to serve any unattended patients, regardless of whether such patients were Medicaid or non-Medicaid. Therefore, the prospect of such a violation constituted good cause and an objectively reasonable basis for the Medical Center to terminate the Agreement.

Appellate Division Holds That a Voluntary Attending Physician Not Employed by a Hospital Cannot Recover for Alleged Retaliation Under New York Labor Law § 741

Deshpande v. Medisys Health Network, Inc., 70 A.D.3d 760, 896 N.Y.S.2d 103 (2d Dep't 2010). Plaintiff, a physician member of the medical staff of the defendant hospital (the "Hospital"), alleged that the Hospital improperly curtailed his privileges in retaliation for his complaints about improper patient care provided by medical residents at the Hospital. Plaintiff sought damages from the Hospital and several Hospital-affiliated defendants (collectively, the "Hospital Defendants") for violation of New York Labor Law § 741, violation of New York common law public policy, and for alleged breach of an implied obligation-in-law of good faith and fair dealing. Plaintiff also sought relief against the Accreditation Council on Graduate Medical Education ("ACGME"), the entity that accredited the Hospital's internal residency program, for negligence and breach of its duty of proper accreditation and enforcement.

The Appellate Division affirmed the dismissal of Plaintiff's claims. Plaintiff could not recover under Labor Law § 741 (also known as New York's Health Care Whistleblower Law) because although he was previously employed by the Hospital, he was not an employee of the Hospital at the time the alleged retaliation occurred. Furthermore, the court held that dismissal was proper because Plaintiff had failed to cite a law, rule or regulation that he in good faith believed the Hospital had violated, as required under § 741.

The court also upheld the dismissal of Plaintiff's remaining claims against the Hospital Defendants because there is no common law cause of action for damages arising from a hospital's wrongful denial of staff privileges. Quoting *Lobel v. Maimonides Med. Ctr.*, 39 A.D.3d 275, 277, 835 N.Y.S.2d 28 (1st Dep't 2007), the court stated that "[W]here a cause of action is based upon an allegedly wrongful denial of hospital privileges, the aggrieved physician is limited to injunctive relief under Public Health Law § 2801-c and is barred by section 2801-b from maintaining an action for damages."

The court also upheld dismissal of Plaintiff's claim against ACGME. Plaintiff had failed to establish the existence of a contract between ACGME and the Hospital under which ACGME would be liable to Plaintiff as a third party.

Appellate Division Affirms Dismissal of Nurse's Whistleblower Retaliation Claim Against Hospital Under New York Labor Law § 741, for Failure to cite a Law, Rule or Regulation That She in Good Faith Believed Had Been Violated

Luiso v. Northern Westchester Hospital Center, 65 A.D.3d 1296, 886 N.Y.S.2d 216 (2d Dep't 2009). Plaintiff, a nurse, brought this suit against her employer, a hospital, pursuant to New York Labor Law § 741, alleging that the hospital removed her from her management position in retaliation for her complaints about the quality of patient care at the hospital.

The Appellate Division upheld summary judgment dismissal of Plaintiff's claims. The court examined Labor Law § 741, which protects employees from retaliation when they disclose or threaten to disclose a "policy or practice…that the employee, in good faith, reasonably believes constitutes improper quality of patient care." N.Y. Lab. § 741(2)(a). "Improper quality of patient care" is defined as "any practice, procedure, action or failure to act of an employer which violates any law, rule, regulation or declaratory ruling adopted pursuant to law" and poses a danger to the health and safety of the public or a specific patient. Plaintiff could not recover under the statute because she was unable to cite any law, rule, regulation or declaratory ruling adopted pursuant to law that she in good faith believed to have been violated.

The court also held that the hospital had demonstrated that its decision to transfer Plaintiff from her management position in the operating room, without any reduction in pay or benefits, was based on her performance as a manager, rather than her complaints about quality of patient care. Notably, Plaintiff acknowledged that she had refused to support certain management policies and requests unrelated to the subject of the quality of patient care.

[Ed. note—Garfunkel Wild, P.C. represented the defendants in the Luiso case.]

Removal of Physician from Participation in Workers' Compensation System Based on Physician's Failure to Maintain Accurate Records Annulled as Arbitrary and Capricious

Matter of Liguori v. Beloten, 26 Misc.3d 593, 888 N.Y.S.2d 737 (Sup. Ct. Albany Cty. 2009). Petitioner, a physician, brought an Article 78 proceeding to annul the New York State Workers' Compensation Board's (the "Board") removal of Petitioner as an eligible medical care provider within the workers' compensation system, due to a reprimand from the New York State Department of Health's Office of Professional Misconduct ("OPMC") for failure to maintain accurate records.

In an OPMC proceeding, Petitioner pled guilty by consent order to failure to maintain accurate records. Specifically, Petitioner was charged for his failure to maintain complete printouts of EEG tests. Petitioner was then subject to a censure and reprimand, among other things. However, Petitioner voluntarily took the further remedial step of purchasing expensive, more up-to-date equipment that would prevent the issue from recurring.

Despite this mitigating factor, and the facts that there were no allegations of patient mistreatment, and that Petitioner had an otherwise spotless record, the Board notified Petitioner that he was no longer eligible to "render medical care to individuals who have suffered work-related injuries or illnesses."

The court annulled the Board's determination as arbitrary and capricious. The court noted that the Board did not give any weight to the fact that Petitioner purchased special equipment in order to keep full records, that no patient care issue was involved, and that Petitioner had an otherwise spotless record.

Noting that Petitioner's removal would result in a 20% decrease in his practice, the court pointed out that "an agency cannot tack on to the prior findings and penalty given by another agency and then argue…that the court must examine their particular punishment in a vacuum, without giving any consideration to the cumulative and highly detrimental effects that both determinations had on an individual."

However, the court denied Petitioner's constitutional claims that his procedural due process rights were violated because his removal occurred without a hearing. The court held that the Board's actions had no impact on Petitioner's medical license and did not deprive Petitioner of any vested liberty interest requiring a notice and hearing.

Limited Liability Companies May Be Convicted of Crimes Committed by Their Employees

People of the State of New York v. Highgate LTC Management, LLC, 69 A.D.3d 185, 887 N.Y.S.2d 298 (3d Dep't 2009). Highgate LTC Management ("Highgate"), a limited liability company ("LLC") that operated a rehabilitation and extended care facility, was convicted of willful violation of health laws and falsifying business records. Highgate appealed the conviction on the grounds that an LLC cannot be held criminally liable for the intentional acts of its employees committed within the scope of their employment, and that the doctrine of

respondeat superior—although specifically applicable to corporations under the Penal Law § 20.20—was not applicable to it because it is technically an LLC.

The Court unanimously upheld the conviction and found that an LLC may be convicted of intentional crimes committed by its employees under certain circumstances. Although Penal Law § 20.20 was not applicable to Highgate per se, the underlying principles of Penal Law § 20.20, upon which the indictment, jury instructions, and conviction were based, nonetheless applied to LLCs, which are legally similar entities to corporations in that they both operate only through their designated agents and employees.

In support of expanding the principles underlying Penal Law § 20.20 to LLCs, the Court cited to *United States v. A & P Trucking Co.*, 358 U.S. 121, 125-26 (1958), which held that "with regard to corporations *and other associations*,…such impersonal entities can be guilty of 'knowing' or 'willful' violations of regulatory schemes through the doctrine of *respondeat superior*." As the Supreme Court explained therein, "the treasury of the business may not with impunity obtain the fruits of violations which are committed knowingly by agents of the entity in the scope of their employment." Thus, absent any distinction recognized by the United States Supreme Court between corporations and LLCs, the Court likewise found that Highgate, as an LLC, may be convicted of intentional crimes under the doctrine of *respondeat superior*.

Moreover, given the public interest at issue and the regulatory nature of the crimes committed, the Court found that there was no rational basis to exempt Highgate from criminal liability, particularly where a similar nursing home corporation would have been held accountable.

Appellate Division Holds That Hospital Had Rational Basis for Suspension of Physician's Clinical Privileges Pursuant to Public Health Law § 2801-c

Tabrizi v. Faxton-St. Luke's Health Care, 66 A.D.3d 1421, 886 N.Y.S.2d 312 (4th Dep't 2009). Petitioner, a physician, sought an injunction under Public Health Law § 2801-c barring the Defendant hospital (the "Hospital") from suspending his clinical privileges.

The Appellate Division affirmed denial of the petition. The Appellate Division found that the Hospital had a rational basis for its suspension of Petitioner's clinical privileges, and that Petitioner had been afforded his full procedural rights pursuant to the Hospital's bylaws.

The Court noted that upon reviewing an application for an injunction pursuant to Public Health Law § 2801-c, the court's inquiry is limited to determining whether the purported grounds for suspending or restricting a physician's practice privileges were reasonably related to the institutional concerns set forth in the statute, whether they were based on the apparent facts as reasonably perceived by the administrators, and whether they were assigned in good faith. Here, the court found that the Hospital's reasons for suspending Petitioner's clinical privileges were properly related to the Hospital's concern for the safety of its patients. In addition, the Hospital's actions were undertaken in good faith, *i.e.*, in response to a telephone call from a physician affiliated with an insurance company who expressed concern over Petitioner's care of a patient insured by that company.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a partner 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

While health care providers on the wrong side of an audit would be hard-pressed to agree, the last several months might make one *almost* sympathetic to the Office of the Medicaid Inspector General (OMIG). (And, for the good of our health care practice, please note the use of the word "almost.")

After a series of *New York Times* exposés alleged that New York State had been asleep at the switch in policing Medicaid fraud, OMIG was created to address what the *Times* suggested might be as much as $18 billion in Medicaid fraud. Now in its fourth year under the direction of Medicaid Inspector James Sheehan, OMIG has certainly had an impact:

- The 2006 F-SHRP Waiver promised $1.5 billion in additional federal fund s subject to New York recovering at least $215 million in Medicaid recoveries in the 2008 fiscal year, $322 million in 2009, $429 million in 2010 and $644 million in 2011—amounts which, at least to date, OMIG has recovered with room to spare. By comparison, Medicaid audit recoveries totaled $39 million in 2003 and $90 million in 2004;
- Faced with a growing state budget deficit, the 2009-10 State Budget raised the ante on Medicaid recoveries above and beyond the F-SHRP targets to $870 million, which OMIG also achieved;
- Given that success and given the State's increasingly dire straits, Governor Paterson this year proposed that OMIG recover still more funds in the next fiscal year, setting a new target of $1.17 billion;

- According to OMIG, recoveries and avoided Medicaid costs increased from $300 million in 2006 to $1.2 billion in 2009-10.

Having met or exceeded its Medicaid recovery totals in an increasingly challenging fiscal environment, one might expect OMIG would be highly popular with Albany elected officials. Not exactly. Growing provider discontent with its practices, somewhat divergent views of its priorities and keen legislative interest in providing more oversight of OMIG have resulted in a series of hearings and a spate of legislative activity designed to redirect or reform OMIG, even as it is required to meet or exceed increasingly large Medicaid recovery targets.

As a result, OMIG is faced with very conflicting challenges, as evidenced by the following: on the one hand, in the (as of this writing) still ongoing debate over the State Budget, the State Senate proposed in its one-house budget resolution to adopt as part of the budget a series of additional due process and other protections for health care providers deemed to be unfairly penalized by OMIG for innocent billing errors. At the same time, the same State Senate budget resolution proposed to increase OMIG's Medicaid recovery target by an additional $300 million.

Current Legislative Activity: In addition to a series of hearings convened by State Senator Craig Johnson that examined OMIG's current practices and procedures, a number of relatively focused bills have been introduced that address OMIG, which can be briefly summarized:

- **A.10047/S.4774 (Weisenberg/Fuschillo)**—The bill requires OMIG to refer suspected fraud or criminality to other prosecutors (e.g., district attorneys) as well as the Attorney General.
- **A.7448-A/S.4218-A (Schimminger/Stachowski)**—The bill prohibits withholding of Medicaid provider payments pursuant to preliminary findings of a pending audit unless the OMIG has made a written finding, based on probable cause, that the provider committed fraud or other criminal conduct involving the claims subject to the audit. The bill is advancing in the Assembly, and remains in the Senate Health Committee.
- **S.6878 (C. Johnson)**—The bill creates a legislative commission to oversee the OMIG on an ongoing basis. The bill is currently in the Senate Committee on Investigations and Government Operations. There is no companion bill in the Assembly.

Moreover, both Assemblyman Richard Gottfried and Senator Craig Johnson have been actively engaged in drafting more comprehensive proposals to address these issues. Senator Johnson had not, as of this writing, introduced separate legislation on these issues, stating that it was the Senate Majority's intention to include OMIG reforms in the (already delayed) State Budget. Assemblyman Gottfried has drafted and introduced a bill that addresses a wide array of issues relating to OMIG and its procedures.

- **A.10630A (Gottfried)**: The bill, which is widely co-sponsored in the Assembly, would:

– Except in the case of alleged fraud or intentional misconduct, preclude OMIG from withholding payments while a hearing is pending;

– Limit audits where another agency has already audited, and prohibit OMIG from applying sanctions that exceed the other agency's sanctions in duration in such cases;

– Require OMIG to abide by guidance to providers issued by other agencies, and allow providers to request the involvement of such agencies in hearings;

– Provide various due process protections in regard to the disclosure of evidence;

– Prohibit OMIG from holding a provider responsible for the failure of another provider or government agency;

– Allow providers a grace period to correct technical errors in claims, and limit recovery where supplies or services have been appropriately provided;

– Limit the use of the extrapolation process and requiring transparency in its application;

– Preclude OMIG from recouping solely because the provider failed to bill within a ninety day period;

– Require OMIG to include interest in repayments to providers for erroneous audit findings;

– Require OMIG, in certain cases, to consider the impact of its actions on accessibility of care;

– Require auditors to have appropriate training and experience;

– Establish a presumption that clinical records are accurate; and

– Clarify the recently imposed requirement for provider compliance programs.

The Legislature has not been monolithic on these issues. The Senate Republicans have, for example, continued to engage the Medicaid fraud issue from a more fiscally driven and anti-fraud and abuse perspective. Senator Kemp Hannon hosted a hearing on March 8, at which a series of local officials and technology providers testified. The hearing and the Senate's subsequent report emphasized the need for OMIG to coordinate enforcement activities with local social service districts and local law enforcement officials, particularly with respect to fraud by Medicaid beneficiaries.

Some of the media reaction to the OMIG legislative activities suggests that the politics of this issue may prove to be somewhat treacherous: for introducing the bill, Assemblyman Gottfried was described by the *New York Post* as the "Fraudsters' Pal." And, given the importance to the already strained State Budget of the funds projected to be recovered by OMIG, any suggestion that these new provisions might negatively affect those recovery targets could well inspire Governor Paterson to veto the measure.

Whatever the outcome of this year's legislative consideration, Medicaid fraud enforcement will continue to garner substantial legislative attention for the foreseeable future—perhaps with even additional force in the advent of federal health reform, which includes provisions to ramp up Medicaid and Medicare fraud enforcement activities for years to come.

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

In the New York State Agencies

By Francis J. Serbaroli

APG Notices

Ambulatory Patient Groups (APG) Outpatient Rate Setting Methodology

Notice of emergency rulemaking. The Department of Health amended Subpart 86-8 of Title 10 N.Y.C.R.R. to refine APG payment methodology regarding new APG weights, new procedure-based weights and minor changes in APG payment rules. Filing date: January 28, 2010. Effective date: January 28, 2010. *See* N.Y. Register, February 17, 2010.

Ambulatory Patient Groups (APGs) Methodology

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Subpart 86-8 of Title 10 N.Y.C.R.R. to modify existing APG transition provisions for new providers and the listing of APG reimbursable and non-reimbursable services. *See* N.Y. Register, March 3, 2010.

Ambulatory Patient Groups (APGs) Methodology

Notice of emergency rulemaking. The Department of Health amended Subpart 86-8 of Title 10 N.Y.C.R.R. to make refinements to APG methodology, including provisions for reimbursement of out-of-state providers. Filing date: March 4, 2010. Effective date: March 4, 2010. *See* N.Y. Register, March 24, 2010.

Ambulatory Patient Groups (APGs) Outpatient Rate Setting Methodology

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend 86-8 of Title 10 N.Y.C.R.R. to refine APG payment methodology regarding new APG weights, new procedure-based weights and minor changes in APG payment rules. *See* N.Y. Register, March 24, 2010.

Cardiac Services

Emergency and Cardiac Services

Notice of Adoption. The Department of Health amended § 405.19 of Title 10 N.Y.C.R.R. by establishing updated minimum standards for Hospital Emergency Services particularly as they relate to patients with Acute Myocardial Infarction (AMI), repealed Subdivisions (d) and (e) of Section 405.22 (Critical Care specific to Cardiac Surgery and Diagnostic Cardiac Catheterization Services), and added a new section 405.29 establishing updated minimum hospital standards for Cardiac Surgery and Cardiac Catheterization Center Services. Filing date: October 20, 2009. Effective date: November 4, 2009. *See* N.Y. Register, November 4, 2009.

Cardiac Services Need Methodology

Notice of Adoption. The Department of Health amended § 709.14 of Title 10 N.Y.C.R.R. to update the need methodology to reflect current practice. Filing date: October 20, 2009. Effective date: November 4, 2009. *See* N.Y. Register, November 4, 2009.

Certificate of Need Process for Cardiac Services

Notice of Adoption. The Department of Health amended § 710.1 of Title 10 N.Y.C.R.R. to align the certificate of need process in cardiac services. Filing date: October 20, 2009. Effective date: November 4, 2009. *See* N.Y. Register, November 4, 2009.

Environmental Issues

Drinking Water State Revolving Fund

Notice of Adoption. The Department of Health amended Part 53 of Title 10 N.Y.C.R.R. to accommodate new requirements from the Federal American Recovery and Reinvestment Act (ARRA) of 2009. Filing date: November 17, 2009. Effective date: December 2, 2009. *See* N.Y. Register, December 2, 2009.

Environmental Testing for Critical Agents Using Autonomous Detection Systems (ADS)

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Subpart 55-2 of Title 10 N.Y.C.R.R. to establish standards for certification of environmental labs using new technologies to analyze samples for critical agents. *See* N.Y. Register, December 9, 2009.

Temporary Residences and Mass Gatherings

Notice of adoption. The Department of Health amended Subpart 7-1 and added Subpart 7-4 to Title 10 N.Y.C.R.R to include removal of requirements for mass gatherings from Subpart 7-1 and relocate those requirements in new Subpart 7-4. Filing date: December 4, 2009. Effective date: December 23, 2009. *See* N.Y. Register, December 23, 2009.

Wastewater Treatment Standards—Residential On-site Systems

Notice of adoption. The Department of Health amended Appendix 75-A of Title 10 N.Y.C.R.R. to revise current standards for residential on-site wastewater treatment systems. Filing date: January 15, 2010. Effective date: February 3, 2010. *See* N.Y. Register, February 3, 2010.

Sexually Transmitted Diseases

HIV Uninsured Care Programs

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Subpart 43-2 of Title 10 N.Y.C.R.R. to allow HIV uninsured care programs to receive and expend funds to provide medications, medical treatment and other supportive services to persons with HIV disease. *See* N.Y. Register, February 3, 2010.

Expedited Partner Therapy to Treat Chlamydia Trachomatis

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 23.4 to Title 10 N.Y.C.R.R. to allow the use of expedited partner therapy to treat the partner of persons infected with Chlamydia Trachomatis. *See* N.Y. Register, April 7, 2010.

Sexually Transmitted Disease (STD) Reporting and Treatment Requirements

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 2.10 and Part 23 of Title 10 N.Y.C.R.R. to require reporting of cases or suspected cases or outbreaks of communicable disease by physicians, list and reporting of STDs. *See* N.Y. Register, April 7, 2010.

Residential Facilities

Criminal History Record Check

Notice of adoption. The Department of Health amended Part 402 of Title 10 N.Y.C.R.R. to establish standards and procedures for criminal history record checks required by statute of certain prospective employees of nursing homes (NHs), certified home health agencies (CHHAs), licensed home health care agencies (LHCSAs) and long-term home health care programs. Filing date: November 17, 2009. Effective Date: December 2, 2009. *See* N.Y. Register, December 2, 2009.

Revisions to Certificate of Need (CON) Process for Threshold Levels

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Parts 405, 410, 420, 600, 703, 705, 709 and 710 of Title 10 N.Y.C.R.R. to constitute the first phase of regulatory changes as part of the Department's review of the CON process. *See* N.Y. Register, March 24, 2010.

Residential Health Care Facility (RHCF) Bed Need Methodology

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 709.3 of Title 10 N.Y.C.R.R. to extend the application of the need methodology to the evaluation of Certificate of Need (CON) applications for the renovation of residential health care facilities (RHCFs), the sale or transfer of RHCF beds between facilities, and changes of ownership of RHCFs that are subject to review by the Public Health Council. *See* N.Y. Register, March 30, 2010.

Insurance Issues

Conduct, Trustworthiness, and Competence of Insurance Producers, Especially Relating to Compensation Arrangements with Insurers

Notice of proposed rulemaking. The Department of Insurance gave notice of its intent to add Part 30 to Title 11 N.Y.C.R.R. to require insurance producers to make certain disclosures about their role in the insurance transaction to insurance customers. *See* N.Y. Register, December 2, 2009

Minimum Standards for the Form, Content and Sale of Health Insurance, Including Standards of Full and Fair Disclosure

Notice of adoption. The Department of Insurance amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to comply with minimum standards for the form, content and sale of health insurance, including standards of full and fair disclosure pursuant to *Benesowitz v. Metropolitan Life Insurance Company*. Filing date: November 19, 2009. Effective date: December 9, 2009. *See* N.Y. Register, December 9, 2009.

Minimum Standards for the Form, Content and Sale of Medicare Supplement Insurance

Notice of emergency/proposed rule making. The Department of Insurance gave notice of its intent to add Part 58 and amend of Parts 52, 215, 360 and 361 of Title 11 N.Y.C.R.R. to conform the regulations with the requirements of federal law. Filing date: February 5, 2010. Effective date: February 5, 2010. *See* N.Y. Register, February 24, 2009.

Financial Statement Filings and Accounting Practices and Procedures

Notice of emergency rulemaking. The Department of Insurance added Part 83 (Regulation No. 172) to Title 11 N.Y.C.R.R. to update the regulation to conform to NAIC guidelines, statutory amendments, and to clarify existing provisions. Filing date: March 25, 2010. Effective date: March 25, 2010. *See* N.Y. Register, April 14, 2009.

Audited Financial Statements

Notice of Emergency Rulemaking. The Department of Insurance repealed Part 89 and added Part 89 (Regulation No. 118) to Title 11 N.Y.C.R.R. to implement provisions of Insurance Law Section 307(b), and add provisions required pursuant to the federal Sarbanes-Oxley Act of 2002. Filing date: March 26, 2010. Effective date: March 26, 2010. *See* N.Y. Register, April 14, 2009.

Payment Issues

Withholding of Payments

Notice of proposed rulemaking. The Office of the Medicaid Inspector General gave notice of its intent

to amend § 518.7(c) and add § 518.9 to Title 18 N.Y.C.R.R. to conform to federal regulations requiring certain information to be set forth in notices of withholdings. *See* N.Y. Register, December 23, 2009.

Hospital Inpatient Reimbursement

Notice of emergency rulemaking. The Department of Health amended Subpart 86-1 of Title 10 N.Y.C.R.R. to modify current reimbursement for hospital inpatient services due to the implementation of All Patient Refined-Diagnostic Related Groups (APR-DRGs) and rebasing of hospital inpatient rates. Filing date: March 4, 2010. Effective date: March 4, 2010. *See* N.Y. Register, March 24, 2010.

Miscellaneous

PASRR SCREEN Requirements

Notice of Adoption. The Department of Health amended § 400.12 of Title 10 N.Y.C.R.R. regarding PASRR SCREEN requirements. The Department removed outdated language; revised incorrect language; and removed SCREEN from regulation text and replaced it with reference. Filing date: October 20, 2009. Effective date: November 4, 2009. *See* N.Y. Register, November 4, 2009.

Personnel Health Amendments and Medicare Conditions of Participation

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 405.3, § 405.9, § 405.10, § 415.26, § 751.6, § 763.13, § 766.11 and § 793.5 of Title 10 N.Y.C.R.R. to allow, but not require, facilities to use Food and Drug Administration (FDA)-approved Blood Assay for tuberculosis (TB) testing in place of the tuberculin skin test, etc. *See* N.Y. Register, December 9, 2009.

Women, Infants, and Children (WIC) Vendor Minimum Stocking Requirements

Notice of adoption. The Department of Health amended § 60-1.13 of Title 10 N.Y.C.R.R. to amend vendor applicant enrollment criteria relative to stocking minimum quantities of WIC acceptable foods. Filing date: December 22, 2009 Effective date: January 6, 2010. *See* N.Y. Register, January 6, 2010.

Circulating Nurse Required

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend § 405.12 of Title 10 N.Y.C.R.R. to require Registered Nurses (RNs) to be assigned and physically present in the operating room when surgery is being performed. *See* N.Y. Register, March 3, 2010.

Early Intervention Program

Notice of revised rulemaking. The Department of Health gave notice of its intent to revise amendments to Subpart 69-4 of Title 10 N.Y.C.R.R. to make several changes to the standards for the provision of services in the Early Intervention Program. *See* N.Y. Register, April 7, 2010

Palliative Care Certified Medical Schools and Residency Programs

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Part 48 to Title 10 N.Y.C.R.R. to define palliative care certified medical schools and residency programs to award grants according to Public Health Law (PHL) § 2807-n. *See* N.Y. Register, April 14, 2010.

Ocean Surf Bathing Beaches and Automated External Defibrillators (AEDs)

Notice of Adoption. The Department of Health amended Subpart 6-2 of Title 10 N.Y.C.R.R. to mandate required ocean surf beaches to be supervised by a surf lifeguard trained in AED operation and provide and maintain on-site AED. Filing date: April 6, 2010. Effective date: April 21, 2010.

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 serves on the Executive Committee of the New York State Bar Association's Health Law Section. The assistance of Whitney M. Phelps and Caroline B. Brancatella of Greenberg Traurig's Health & FDA Business Group in compiling this summary is gratefully acknowledged.

In the Journals

American Journal of Law & Medicine, Vol. 35:3 (2009)

- *"Monitoring" Corporate Corruption: DOJ's Use of Deferred Prosecution Agreements in Health Care,* Kathleen M. Boozang, Simone Handler-Hutchinson
- *And Health Care For All: Immigrants in the Shadow of the Promise of Universal Health Care*, Adrianne Ortega
- *Retail Health Clinics: How the Next Innovation in Market-Driven Health Care is Testing State and Federal Law*, Kaj Rozga

American Journal of Law & Medicine, Vol. 35:4 (2009)

- *Legal Impediments to Implementing Value Based Purchasing in Healthcare,* Anne B. Claireborne, Julia R. Hesse, Daniel T. Roble
- *Medical Error and Tort Reform through Private Contractually-Based Quality Medicine Societies,* Duncan MacCourt, Joseph Bernstein
- *Hastening Death: Dying, Dignity and the Organ Shortage Gap,* Wojciech Baginski
- *From Concierge Medicine to Patient-Centered Medical Homes: International Lessons and the Search for a Better Way to Deliver Primary Health Care in the U.S.,* Gwendolyn Roberts Majette
- *Beyond Politics: A Social and Cultural History of Federal Healthcare Conscience Protections,* Kimberly A. Parr
- *But Doctor, I Still Have Both Feet!: Remedial Problems Faced by Victims of Medical Identity Theft*, Katherine Sullivan

Annals of Health Law (Loyola U. Sch. of L.) Vol. 19 No. 1 & 2 (2010)

- *Wither the Next Phase of Health Law?*, Ed Bryant
- *What I Talk About When I Talk About Health Law*, Elizabeth Weeks
- *Health Care Law: A Field of Gaps*, David Orentlicher, M.D., J.D.
- *Twenty-Five Years of Health Law Through the Lens of the Civil False Claims Act*, Joan H. Krause
- *Health Law Past and Future: Looking for Stability in All the Wrong Places*, Peter D. Jacobson, J.D., M.P.H.
- *Toward a More Just Health Care System*, Kayhan Parsi, J.D., Ph.D.
- *Does Twenty-Five Years Make a Difference in "Unequal Treatment"?: The Persistence of Racial Disparities in Health Care Then and Now*, Ruqaiijah Yearby
- *The Aftermath of Federal Health Care Reform: The Challenge for States and the Private Sector*, Lawrence E. Singer
- *Breaking Down the Federal and State Barriers Preventing the Implementation of Accurate, Reliable, and Cost Effective Electronic Health Records*, Stephen J. Weiser, J.D., LL.M.
- *Finding a New Regulatory Pathway for the Old Labyrinth of Health Planning*, John D. Blum, J.D., M.H.S.
- *The "Stark" Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?*, Paula Tironi
- *The Impact of Federal Regulations on Health Care Operations*, Piya M. Gasper, J.D., M.P.H.
- *A Call for Minds: The Unknown Extent of Societal Influence on the Legal Rights of Involuntarily and Voluntarily Committed Mental Health Patients,* Teresa Cannistraro (2010)
- *Imperfect Remedies: Legislative Efforts to Prevent Genetic Discrimination,* Timothy J. Aspinwall
- *Genetic Testing, Physicians and the Law: Will the Tortoise Ever Catch Up with the Hare?,* Lee Black, J.D., LL.M., Jacques Simard, Ph.D., Bartha Maria Knoppers, Ph.D.
- *Hospital-Physician Partnerships: The Drivers, the Obstacles and the Benefits,* Elissa Koch Moore, Loyola University Chicago School of Law
- *Life-Sustaining Treatment and the Law: The Evolution of Informed Consent, Advance Directives and Surrogate Decision Making,* Joseph T. Monahan, M.S.W., A.C.S.W., J.D., Elizabeth A. Lawhorn
- *Post-Mortem Pregnancy: A Proposed Methodology for the Resolution of Conflicts Over Whether a Brain Dead Pregnant Woman Should be Maintained on Life-Sustaining Treatment*, Alexis Gregorian
- *Medicare: It's Time to Talk About Changing It,* Cynthia E. Boyd
- *Fee-for-Disservice: Medicare Fraud in the Home Healthcare Industry*, Brooke Benzio

Houston Journal of Health Law & Policy, Vol. 10 (2010)

- *What Happened to No Fault? The Role of Error Reporting in Healthcare Reform*, Henry Huan, Farzad Soleimani
- *Health Care Reform & The Missing Voice of Complementary and Alternative Medicine*, Gwendolyn Roberts Majette

Journal of Health & Biomedical Law, Vol. 5 (2009)

- *Health Care Debate: Aligning Health Care Market Incentives in an Information Age: The Role of Antitrust Law,* Taylor Burke, Sara Rosenbaum
- *Case Comment: Hospital Liabilit—Non-Patients Have Standing to Sue Under EMTALA, Which Requires More Than Mere Inpatient Admission—Moses v. Providence Hosp. & Med. Ctrs., Inc., 561 F.3d 573 (6th Cir. 2009),* Ilenna Elman Stein

Journal of Health & Life Sciences Law (American Health Lawyers Assn), Issue 3, No. 2 (April 2010)

- *Regulatory Issues Facing Genetic Testing*
- *Health Law Hitchhiker's Guide to the Internet*

Journal of Health & Life Sciences Law (American Health Lawyers Assn), Issue 3, No. 3 (April 2010)

- *Marketing Approval versus Cost of New Medical Technologies in the Era of Comparative Effectiveness: CMS, not FDA, Will Be the Primary Player,* Bruce Patsner
- *Undocumented Immigrants, Healthcare Access, and Medical Repatriation Following Serious Medical Illness,* Maya A. Babu, Joseph B. Wolpin
- *Off With Their Heads! Summary Execution for Technical Stark Violations—and a Proposal to Commute the Sentence,* Robert C. Lower, Robert D. Stone
- *Compliance Officer Roundtable: American Health Lawyers Association Fraud and Compliance Forum,* Alana B. Sullivan, Kim Lansford,, Sara Kay Wheeler

Journal of Law, Medicine & Ethics, Vol. 37:2 (2009)

Symposium: Special Supplement: Legal Solutions in Health Reform:

- *Executive Authority to Reform Health: Options and Limitations*, Madhu Chugh
- *The Constitutionality of Mandates to Purchase Health Insurance*, Mark A. Hall
- *Health Insurance Exchanges: Legal Issues*, Timothy Stoltzfus Jost
- *Tax Credits for Health Insurance*, Fred T. Goldberg Jr., Susannah Camic
- *The Role of ERISA Preemption in Health Reform: Opportunities and Limits*, Peter D. Jacobson
- *An Overview of Discrimination Practices, Federal Law, and Federal Reform Options*, Sara Rosenbaum
- *Privacy and Health Information Technology*, Deven McGraw
- *The Purchase of Insurance Across State Lines in the Individual Market*, Stephanie Kanwit

Journal of Law, Medicine & Ethics, Vol. 37:3 (Fall 2009)

Symposium: Special Supplement: Dangerous Liaisons? Industry Relations with Health Professionals:

- *Altruism and Self Interest in Medical Decision Making,* Paul H. Rubin
- *Better Regulation of Industry-Sponsored Clinical Trials Is Long Overdue*, Matthew Wynia, David Boren
- *More Regulation of Industry-Supported Biomedical Research: Are We Asking the Right Questions?*, Sigrid Fry-Revere, David Bjorn Malmstrom
- *Drug Reps Off Campus! Promoting Professional Purity by Suppressing Commercial Speech*, Lance K. Stell
- *DTC Advertising Harms Patients and Should Be Tightly Regulated*, Peter Lurie
- *Pharmaceutical Industry Financial Support for Medical Education: Benefit, or Undue Influence?*, Howard Brody

Journal of Law, Medicine & Ethics, Vol. 37:4 (Winter 2009)

Symposium—Developing Oversight Approaches to Nanobiothechnology: The Lessons of History

Journal of Law, Medicine & Ethics, Vol. 38:1 (Spring 2010)

Symposium—The Effects of Health Information Technology on the Physician-Patient Relationship

- *The Hippocratic Bargain and Health Information Technology*, Mark A. Rothstein
- *Health IT and Solo Practice: A Love-Hate Relationship,* Joseph Heyman
- *The Impact of Web 2.0 on the Doctor-Patient Relationship*, Bernard Lo, Lindsay Parham
- *Health Information Technology and the Idea of Informed Consent*, Melissa M. Goldstein
- *The Physician-Patient Relationship and a National Health Information Network*, Leslie Pickering Francis

- *Ethics, Information Technology, and Public Health: New Challenges for the Clinician-Patient Relationship*, Kenneth W. Goodman
- *Dreams and Nightmares: Practical and Ethical Issues for Patients and Physicians Using Personal Health Records*, Matthew Wynia, Kyle Dunn
- *Prescription Data Mining and the Protection of Patients' Interests*, David Orentlicher
- *Currents in Contemporary Ethics: Malpractice Immunity for Volunteer Physicians in Public Health Emergencies: Adding Insult to Injury*, Mark A. Rothstein
- *Independent Article: State Tort Reforms and Hospital Malpractice Costs,* Charles R. Ellington, Martey Dodoo, Robert Phillips, Ronald Szabat, Larry Green, and Kim Bullock
- *Teaching Health Law: A Service Learning Project: Disability, Access, and Health Care*, Elizabeth Pendo

NYS Bar Assn Health Law Journal, Vol. 14, No. 2 (Winter 2009)

Conversations, Edited by Peter J. Millock

- *A Conversation About Hospital Combinations*, Peter J. Millock, Robert Hall Iseman, Richard M. Cook, John F. (Jack) Gleason, Robert Wild
- *A Conversation About Medical Malpractice*, Martin Bienstock, Edward Amsler, Bruce G. Clark, Susan C. Waltman
- *A Conversation About Fraud and Abuse*, Edward S. Kornreich, James G. Sheehan, Mark W. Thomas, Marcia B. Smith, Sean Cenawood, Rebecca Martin, Heidi Wendel
- *A Conversation About Health Care Reform*, James W. Lytle, Richard Gottfried, Elisabeth Benjamin, David Rich, Melinda Dutton
- *A Conversation About End-of-Life Decisionmaking*, Alicia Oullette, Timothy E. Quill, M.D., Robert N. Swidler, Thaddeus M. Pope, Nancy Dubler
- *A Conversation About Difficult Inpatient Discharge Issues*, Robert N. Swidler, Alyssa M. Barreiro, James D. Horwitz, James Fouassier, Rachel Goldberg, Marguerite Massett, Pamela Tindall O'Brien

Section Matters

- *Summary Report on Healthcare Costs: Legal Issues, Barriers and Solutions*, NYS Bar Assn Health Law Section

Journal of Health Care Law & Policy, Vol. 12 (2009)

Symposium: Ethics of Health Care Law Reform

- *The Ethical Foundations of Consumer Driven Health Care,* Marshall B. Kapp, J.D.
- *Expanding the Current Health Care Reform Debate: Symposium: Making the Case for Socio-Economic Interventions for Low Income Young Adults*, Namrata Kotwani, B.A., Marion Danis M.D.
- *Privacy and Confidentiality in the Age of E-Medicine,* Keith A. Bauer, MSW, Ph.D
- *Unintended Consequences of Payment Schemes and Regulatory Mandates*, Rebecca D. Elon, M.D., M.P.H.
- *Service by Health Care Providers in a Public Health Emergency: The Physician's Duty and the Law*, Judith C. Ahronheim, M.D.

Yale Journal of Health Policy, Law, Vol. 10 (2010)

- *Recalibrating the Legal Risks of Cross-Border Health Care,* Nathan Cortez
- *Implications of Genetic Testing for Health Policy,* Gregory Katz, Stuart O. Schweitzer
- *From a Constitutional Right to a Policy of Exceptions:* Abigail Alliance *and the Future of Access to Experimental Therapy,* Seema Shah, Patricia Zettler
- *Pay or Play Programs and ERISA Section 514: Proposals for Amending the Statutory Scheme,* Christen Linke Young

Other Law Journals

- *2007-2008 Survey of New York Law: Health Law,* Edward F. McArdle, Matthew J. VanBeveren, 59 Syracuse L. Rev. 861 (2009)
- *Advocacy in Health Proceedings in New York State*, Kia C. Franklin, 25 Touro L. Rev. (2009)
- *Altered Standards of Care for Health Care Providers in the Pandemic of Influenza*, Eleanor D. Kinney, 6 Ind. Health L. Rev. 1, (2009)
- *Answering the Millennium Call for the Right to Maternal Health: The Need to Eliminate User Fees*, Margaux J. Hall, Aziza Ahmed, Stephanie E. Swanson, 12 Yale H.R. & Dev. L.J. 62 (2009)
- *Biotechnology and Embryonic Stem Cells: A Comparative Analysis of the Laws and Policies of the United States and Other Nations*, Andrew McCoy, 8 Loy. Law & Tech. Ann. 63 (2009)
- *Can Health Care Conscientious Objectors Thread the Needle?,* Leonard J. Long, 13 Quinnipiac Health L.J. 51 (2009)

- *Cascade Health Solutions v. Peace Health*, Sara Shouse, 53 N.Y.L. Sch. L. Rev. 335 (2008/2009)
- *Comparative Architecture of Genetic Privacy*, Khadija Robin Pierce, 19 Ind. Int'l & Comp. L. Rev. 89 (2009)
- *Credentialing and Peer Review: A Primer for the Non-Health Care Attorney,* Calvin L. Raup, 46 AZ Attorney 30 (2010)
- *Crisis on Campus: Student Access to Health Care*, Bryan A. Liang, 43 U. Mich. J.L. Reform 617 (2010)
- *Election of Remedies in the Twenty-First Century: Centra Health, Inc. v. Mullins,* L. Steven Emmert, 44 U. Rich. L. Rev. 149 (2009)
- *Equitable Prescription Drug Coverage: Preventing Sex Discrimination in Employer-Provided Health Plans*, Stephen F. Befort, Elizabeth C. Borer, 70 La. L. Rev. 205 (2009)
- *Equity in Reforming the Tax Treatment of Health Insurance Premiums*, Janene R. Finley, Amanda M. Grossman, 34 Seton Hall Legis. J. 1. (2009)
- *Evanston's Legacy: A Prescription for Addressing Two-Stage Competition in Hospital Merger Antitrust Analysis,* Erica L. Rice, 90 B.U.L. Rev. 431 (2010)
- *Four Problems Facing Meaningful State Health Care Reform and Coverage in the United States*, Arlene Akiwumi-Assani, 72 Alb. L. Rev. 1077 (2009)
- *Fulfilling the Promise of the Medicaid Act: Why the Equal Access Clause Creates Privately Enforceable Rights,* Sean Jessee, 58 Emory L.J. (2009)
- *Health Care & Pharmaceuticals: Health Care Reform and the Logic of Emergence*, M. Gregg Bloche, Sujata M. Jhaveri, 11 Minn. J.L. Sci. & Tech. 193 (2010)
- *Health Care & Pharmaceuticals: Open Source Drug Development: A Path to More Accessible Drugs and Diagnostics?,* Emily Marden, 11 Minn. J.L. Sci. & Tech. 217 (2010)
- *Health Care Law,* Kathleen M. McCauley, Kristi L. Vander-Laan, 44 U. Rich. L. Rev. 473 (2009)
- *How the "Improvement Standard" Improperly Denies Coverage to Medicare Patients with Chronic Conditions*, Gill Deford, Margaret Murphy, Judith Stein, Sargent Shriver National Center on Poverty Law, 43 Clearinghouse Rev. 422 (2010)
- *Insuring Fairness: The Popular Creation of Genetic Antidiscrimination*, Jeffrey S. Morrow, 98 Geo. L.J. 215 (2009)
- *Involuntary Outpatient Commitment: Some Thoughts on Promoting a Meaningful Dialogue Between Mental Health Advocates and Lawmakers*, Henry A. Dlugacz, 53 N.Y.L. Sch. L. Rev. 79 (2008/2009)
- *Making the Plaintiff's Bar Earn its Keep: Rethinking the Hospital Incident Report*, Katherine Mikk, 53 N.Y.L. Sch. L. Rev. 133 (2008/2009)
- *Neuroscience and Health Law: An Integrative Approach?*, Stacey A. Tovino, 42 Akron L. Rev. 469 (2009)
- *Opacity and Cost Effectiveness Analysis in Medicare Coverage Decisions: Health Policy Encounters Administrative Law*, Michael S. Kobler, 64 Food Drug L.J. 515 (2009)
- *Open Source and Proprietary Models of Innovation: Beyond Ideology: PART III: Open Source and Proprietary Software Development: Slouching Toward Open Innovation: Free and Open Source Software for Electronic Health Information*, Greg R. Vetter, 30 Wash. U. J.L. & Pol'y 179 (2009)
- *Planning for Alzheimer's Disease with Mental Health Advance Directives*, Lisa Brodoff, 17 Elder L.J. 239 (2010)
- *Playing Games with Girls' Health: Why It Is Too Soon to Mandate the HPV Vaccine for Pre-Teen Girls as a Prerequisite to School Entry*, Julie E. Gendel, 39 Seton Hall L. Rev. (2009)
- *Playing the Odds or Playing God? Limiting Parental Ability to Create Disabled Children Through Preimplantation Genetic Diagnosis*, Karen E. Schiavone, 73 Alb. L. Rev. 283 (2009)
- *Preempting Discrimination: Lessons from the Genetic Information Nondiscrimination Act*, Jessica L. Roberts, 63 Vand. L. Rev. 439 (2010)
- *Preparing for Pandemic Influenza: Clinical Research in a Public Health Crisis: The Integrative Approach to Managing Uncertainty and Mitigating Conflict*, Alex John London, 39 Seton Hall L. Rev. (2009)
- *Price Wars and Patent Law: Reducing the Cost of Health Care Through Medical Device Price Transparency*, Asha S. Geire, 12 Tul. J. Tech. & Intell. Prop. 239 (2009)
- *Privacy and Security of Personal Health Records Maintained by Online Health Services,* Jenna Caldarella, 20 Alb. L.J. Sci. & Tech. 203 (2010)

- *Roe's Life-or-Health Exception: Self-Defense or Relative-Safety?*, Stephen G. Gilles, 85 Notre Dame L. Rev. 525 (2010)
- *Symposium on Health Care Technology: Regulation and Reimbursement: Economic Parameters of End-of-Life Care: Some Policy Implications in an Era of Health Care Reform*, Michael Ash, Stephen Arons, 31 W. New Eng. L. Rev. 305 (2009)
- *Symposium on Health Care Technology: Regulation and Reimbursement: Regulating Direct-to-Consumer Advertising With Tort Law: Is the Law Finally Catching Up With the Market?*, Timothy S. Hall, 31 W. New Eng. L. Rev. 333 (2009)
- *Symposium on Health Care Technology: Regulation and Reimbursement Opening the Door to "Hard-Look" Review of Agency Preemption*, Karen A. Jordan, 31 W. New Eng. L. Rev. 353 (2009)
- *The §363 Miracle Drug? Potential Restrictions and Challenges of Selling Hospitals in Bankruptcy*, Gus Kallergis, 28-9 ABI Journal 14, (2009)
- *The Academic Medical Center Exception to the Stark Law: Compliance by Teaching Hospitals*, Jennifer A. Hanson, 61 Ala. L. Rev. 373 (2010)
- *The Continuing Viability of Medicaid Rights After the Deficit Reduction Act of 2005*, Harper Jean Tobin, Rochelle Bobroff, 118 Yale L.J. Pocket Part 147 (2009)
- *The Deficit Reduction Act of 2005- Reducing the Number of Recipients and Applicants Eligible to Receive Medicaid Benefits*, Christal Contini, 22 J.L. & Health 405 (2009)
- *The Law and Policy of Health Care Quality Reporting*, Kristin Madison, 31 Campbell L. Rev. 215 (2009)
- *The Public's Right to Health: When Patient Rights Threaten the Commons*, Elizabeth Weeks Leonard, 86 Wash. U. L. Rev. 1335 (2009)
- *To Pay or Not to Pay: Medicare and the Preventable Adverse Event: A Rational Decision or Dangerous Philosophical Change?*, Amy J. Chaho, M.D., 22 J.L. & Health 91 (2009)
- *Will Americans Embrace Single-Payer Health Insurance: The Intractable Barriers of Inertia, Free Market, and Culture*, Susan Adler Channick, 28 Law & Ineq. 1 (2010)
- *You Can Take This Health Insurance and… Mandate It?*, Daniel Gottlieb, 33 Seton Hall Legis. J. 535 (2009)

Compiled by the Editor, with the assistance of Allison Gold.

For Your Information

By Claudia O. Torrey

Whether or not you were "for" the recently enacted Patient Protection and Affordable Care Act ("Act"), one must agree that implementation or "roll out" of its provisions will be important to its acceptance! While there are provisions of the Act that become effective in 2014, a number of Act provisions "come to life" in 2010; for example: health care coverage for young adults less than twenty-six years old via their parent's policy; phasing out the prescription "doughnut hole" under Medicare Part D; increasing availability of student loans for medical students going into primary care; strengthening anti-kickback laws; increased funding for diversity training and cultural competency; tax credits to small employers that offer employee health insurance; and the establishment of grant programs for the recruitment and training of rural physicians.

As we become a more global health care workforce (more and more health care providers, both for-profit and non-profit, are expanding their reach outside of the United States borders), some of the above stated provisions will be a critical benefit! This author also suggests that the enactment of the Act presents an opportunity for health care providers, as well as liability insurers, to vigorously promote both quality over quantity and compassion regarding medical errors and malpractice reform.[1] These entities should not wait for tort reform at the state or federal level, but be in the vanguard of "doing what is right."

In February 2010, the case of *Lebron v. Gottlieb*[2] sent a clarion call for innovation in the area of malpractice reform. Foreclosing lawsuits would not be the goal because we all know that physicians should not prosper from either doing too little or too much for their patients; however, given the provisions in the new Act, we are all stakeholders in this "new prescription."

Endnotes

1. Kraman S.S., Hamm G., *Risk Management: Extreme Honesty May Be The Best Policy*, Ann. Intern. Med., 131: 963-967(1999).
2. 2010 WL 375190 (Ill. 2010) (The Illinois Supreme Court held that the State's cap on non-economic damages violated the Illinois Constitution.).

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Implementing Federal Health Care Reform: Managing Challenges, Opportunities, and Preparing for Inevitable, Unintended Consequences

By Susan Van Meter and Jeffrey Gold

Introduction

The long-awaited passage of federal, comprehensive health care reform[1] is unquestionably a momentous step in the direction of securing universal coverage and instituting insurance market reform that will make a real difference in the lives of Americans. The Patient Protection and Affordable Care Act also enacts hospital and continuing care delivery system reform that promises to improve patient care delivery and "bend the cost curve." Insurance market reform provisions will affect providers, though the provisions will not protect against increased pressure on hospitals and continuing care providers in the form of tougher rate negotiations and ongoing unfair insurer tactics in the marketplace.

Over the next several years, the hospital and continuing care community in New York and throughout the nation will begin the ambitious task of implementing these reform initiatives against a backdrop of legislated, long-term reductions in Medicare and Medicaid reimbursement. New York hospitals, hospital-based skilled nursing facilities, home health agencies, and hospices will face approximately $13.5 billion in cuts over the next ten years.[2] Though hospitals will experience revenue increases as coverage expansion begins to take hold in 2014, reductions begin right away, and many hospitals expect the cuts to outstrip the value of any revenue increases.

Delivery system reform offers hospitals and continuing care providers a promising path toward much-needed integration of care delivery and alignment of financial incentives, but this path is fraught with structural and resource challenges. To avoid missteps, providers will need to think and plan strategically for the implementation of Medicare value-based purchasing (VBP), a readmissions payment policy, and take advantage of—or make a leap of faith and join—the voluntary Medicare "bundling" pilot and the voluntary Medicare Shared Savings (Accountable Care Organization) program. Providers must also monitor closely and consider participating in testing of new delivery system reforms that will be developed under an entity that may be among the most underappreciated provisions in the law—the establishment of the Center for Medicare and Medicaid Innovation (CMI).

When it comes to implementing health care delivery system reform and seizing its opportunities, hospitals and continuing care providers currently part of integrated systems have a leg up compared to providers whose institutional structures and relationships mirror the overall fragmented nature of our health care delivery system. Developing these institutional relationships or bolstering those that already exist and making strategic decisions regarding taking on more risk will be critical for providers, who must move implementation forward with diminishing resources.

"The long-awaited passage of federal, comprehensive health care reform is unquestionably a momentous step in the direction of securing universal coverage and instituting insurance market reform that will make a real difference in the lives of Americans."

This article discusses the opportunities and challenges associated with implementing the new health reform law's Medicare and Medicaid payment reductions and delivery system reform provisions affecting hospitals and continuing care providers. We explore how the health insurance reform in the law, which clearly benefits patients, may have both positive and negative results for providers. In addition, we offer examples of possible unexpected consequences that must be addressed.

Medicare Delivery System Reform

The new federal health care reform law contains a number of delivery system reform provisions hospitals will be required to implement under the Medicare program, chiefly inpatient VBP and a policy that would penalize hospitals for preventable readmissions.

Additional delivery system reform includes a voluntary pilot for Medicare payment "bundling" of acute and post-acute care services, and the voluntary Accountable Care Organization (ACO) program that will enable providers to share in the cost savings they achieve for the Medicare program in serving a defined patient population. In addition, providers will be able to participate in testing of new delivery system reforms that will be developed under the new CMI.

The Secretary of Health and Human Services (HHS) has the authority to extend these programs should they prove to maintain or improve quality and decrease cost.

While some critics have complained that the delivery system reform in the new law does not go far enough, it will indeed be the case that within a short period, major inpatient payment changes will occur, designed to incentivize improved care. These are the most significant payment changes since the advent of the inpatient Medicare Prospective Payment System in 1984.

The decision to begin some reform initiatives as voluntary pilot programs was practical and shrewd. A "one-size-fits-all" mandate would not work because providers and communities are so diverse. The health care delivery system varies from community to community within New York and across the nation. Fee-for-service medicine is still the norm, with physicians, other practitioners, and providers across the continuum largely functioning independently—even within integrated systems. To transform the delivery system into an integrated and interdependent system with providers paid on a global basis, such as through an ACO, would be disruptive and unachievable in most communities. Allowing for the development of different models over time holds a greater promise of success.

Paying for Reform

The hospital field pressed the Obama Administration and Congress not to use delivery system reform proposals as a guise for reduced reimbursement, yet the savings that can accrue from these polices should be recognized. Throughout the year-long process of developing the legislation, hospitals maintained that delivery system reform, thoughtfully designed, holds the promise of improving the quality of care delivered and the coordination of that care, while creating efficiencies that should generate savings over time.

Regrettably, the Congressional Budget Office (CBO) does not score such proposals in a dynamic fashion. Unless it is a reduction that can be measured or written into law, CBO does not recognize it as a scoreable "saver." The promise of reducing costs through delivery system reform was largely not quantified or considered part of the hospital and continuing care field's contribution to the cost of coverage expansion.

Instead, raising revenue from the hospital field will be accomplished through straightforward Medicare and Medicaid payment reductions.

One of the few tenets for reform the President put forward early on and insisted upon throughout the legislative process was that the legislation's cost be fully offset. His approach was one of ensuring a spirit of shared responsibility among providers, insurers, pharmaceutical makers, device manufacturers, individuals, employers, taxpayers, and other stakeholders. The major national hospital associations stood behind the spirit of shared responsibility and were willing to accept a level of payment reductions to fund coverage expansion, since near universal coverage was expected to yield increased revenue to hospitals over the long term. However, many of the provider cuts will occur before coverage expansion takes hold.

One can argue about whether the entire bill is truly offset over the long term, but one thing is clear: by the standards of large, complex bills, this one strives to be fiscally responsible in a global sense. Consider the more than $500 billion Medicare prescription drug bill passed in 2003, of which not one dollar was offset.

Medicare Inpatient Hospital Value-Based Purchasing[3]

The Medicare VBP provision included in the new law adheres to a principle important to the hospital community: the policy is designed to produce incentives to improve overall performance and quality outcomes, and is not a tool to reduce Medicare's overall level of reimbursement to hospitals nationwide. The program is budget-neutral, where the total of funding drawn from hospitals to create the VBP incentive pool will be paid out in the same year as incentive payments. Earlier proposals, including one the President put forward in early 2009, called for a VBP policy designed to dramatically reduce inpatient hospital spending by $12 billion over ten years.

Beginning in federal fiscal year (FFY) 2013, a percentage of inpatient payment will be tied to hospital performance on quality measures related to common and high-cost conditions, such as cardiac, surgical, and pneumonia care. Another important attribute is that a hospital can receive credit toward an incentive payment not only for achieving a performance standard, but also for showing measureable improvement toward that standard.

Hospitals will receive higher scores, and therefore greater incentive payments, if they are able to achieve or surpass the performance standards, not just show improvement toward them. An important modification to this policy moving forward must be to better ensure that payment penalties do not increase inequality in health care delivery by reducing poor performers' resources, preventing them from investing in the steps necessary to improve quality.

The HHS Secretary must submit plans for the development of VBP programs for skilled nursing facilities and home health agencies to Congress by October 1, 2011, and for ambulatory surgical centers by January 1, 2011.

Medicare Inpatient Hospital Readmissions[4]

The law's Medicare hospital readmissions payment policy will impose severe payment penalties for a provider's inability to meet norms determined by the HHS Secretary—hospitals nationwide will be subject to more than $7 billion in Medicare reductions over ten years.

A far better approach would be to provide positive incentives for the provision of high-quality care—ensuring

that providers facing the greatest challenges to improving care, and those continually striving to achieve excellence, are afforded the opportunities and resources to do so.

Under the provision, beginning in FFY 2013, hospitals' actual 30-day post-discharge readmissions rates will be compared to their expected readmissions rates initially for three conditions (heart attack, heart failure, and pneumonia) and any hospital with even one readmission more than expected will be financially penalized. These penalties will be applied to every single Medicare discharge, not just discharges for the three conditions actually being measured. The Secretary has the authority to expand the list of conditions to which the policy applies, including all-cause readmissions.

The Secretary is required to establish a quality improvement program for hospitals with the highest readmissions rates, and patient safety organizations will work with hospitals to reduce these rates. Nonetheless, the high level of savings associated with the provision is cause for concern, particularly for hospitals in areas with pockets of poverty, where the community infrastructure necessary to support patients upon discharge may be inadequate to positively affect change.

Of further concern is the failure of this policy to effectively differentiate between avoidable readmissions and those that are widely considered unavoidable, such as those associated with chronic conditions and specific diseases for which readmissions are required. Many readmissions may be unavoidable due to factors such as the natural progression of the underlying disease and the complex nature of the patient's condition.

The science behind hospital readmissions is nascent. Researchers are beginning to uncover the multitude of variables that may influence whether a patient is readmitted to a hospital; yet, we remain far from understanding how, when, and to what degree these variables matter and how to diminish their impact.

Moving forward, the readmissions policy must be modified to remove its punitive character and to focus exclusively on cases of unplanned and preventable readmissions related to the initial admission (e.g., a patient is admitted for an emergency appendectomy, discharged, and then readmitted the following week for a surgical site infection). The list of specific exclusions from any readmissions policy should be expanded to include psychoses, maternity, neonatal, substance abuse, and end-stage renal disease.

The HHS Secretary should be required to conduct research into variables likely to influence readmissions rates, such as socio-economic status, patient compliance, and access in the community to timely primary/ambulatory follow-up care. From this research, a non-clinical risk adjustor should be developed and applied, in addition to the clinical risk adjuster required under the law.

Medicare Acute/Post-Acute Payment Bundling Pilot[5]

The goal of bundling payments is to incentivize providers to act in concert to coordinate care, creating efficiencies and improving care delivery. Participating providers accept a degree of "performance risk" for certain episodes of care and gain the benefits of increased collaboration with other providers and new efficiencies in care delivery. Bundling has not yet been put into practice in broad-based ways among varied care delivery systems with either public or private payers.

By January 1, 2013 the Secretary must implement a national, budget-neutral, voluntary pilot program of bundled acute and post-acute payments for an "episode of patient care" using ten conditions. The episode will likely be from three days prior to hospital admission, extending through 30 days following discharge, though the Secretary has authority to define an episode otherwise. The bundled payment will cover:

- acute care inpatient services, including readmissions;
- outpatient hospital services, including emergency room;
- physician care, including services in and out of the hospital; and
- post-acute care, including home health services, skilled nursing facility, inpatient rehabilitation, and long-term care hospital services.

An entity comprised of providers and suppliers, including a hospital, physician group, skilled nursing facility, and home health agency could submit an application to join the pilot program. The Secretary will develop bundled payment rates and test them based on bids from the entities. Annual payments under the pilot to a single entity may not exceed what would otherwise be paid for the same services under the current Medicare program.

While the initial duration of the pilot program is five years, in a last-minute change made in the "manager's amendment" just prior to vote on the legislation in the U.S. House of Representatives, the Secretary was given broad authority to expand the pilot program's scope and duration any time after January 1, 2016, if certain conditions are met. Those conditions are that she and the Chief Actuary of the Centers for Medicare and Medicaid Service (CMS) determine that doing so is expected to reduce Medicare spending, preserving or improving the quality of care, while ensuring that such expansion would not diminish coverage or benefits for beneficiaries. Typically, when Congress provides the authority for a new pilot program, the Secretary must make the case to Congress that the pilot should be expanded and extended and she must wait for Congress to legislate the changes. The Secretary will not be slowed down by having to clear this hurdle.

Health care providers and suppliers should not wait for the Secretary's issuance of the request for proposals (RFP) to begin discussing within their own organizations and among stakeholders the possibilities for collaboration and application to this pilot program.

The Secretary is to consult with Critical Access Hospitals and small rural hospitals regarding their participation in the program and what methods might be used to integrate them into the pilot, given the low volume of services they provide.

Crucial to the success of this program is the degree to which its design eliminates existing legal barriers to clinical integration. Under the law, the Secretary has the authority to waive provisions of Titles XI and XVIII of the Social Security Act—that is, the False Claims, Anti-kickback, Stark (self-referral), and Civil Monetary Penalty group of laws, as well as the more general provisions of Medicare—to implement the pilot program. The extent to which the Secretary will act on this authority will become clear when she issues the formal RFPs for the pilot program. Providers and suppliers must be vigilant in their consideration of how the pilot is designed with regard to fraud and abuse laws and regulations attached to the Medicare and Medicaid programs.

For those laws and regulations clearly beyond the Secretary's authority to waive—such as those related to antitrust—a key question is whether those laws and policies represent an actual impediment to a pilot program. If so, the Secretary will need to consider whether waiver authority will be needed or if other arrangements need to be made with the agencies with jurisdiction over these laws.

Hospitals and continuing care providers already part of an integrated system, particularly those that employ physicians, stand the greatest chance of meeting the likely requirements for the pilot program and are best prepared to take on new risk. In an environment of limited resources, freestanding providers lacking those institutional arrangements will encounter significant challenges in developing an application for the pilot.

The Secretary should take great care to develop program parameters that will not only allow those currently best suited to enter the pilot program, but also those providers for which a freestanding institutional structure may otherwise preclude them from exiting the fee-for-service paradigm, taking on more risk, and responding to incentives to improve care delivery.

In addition to accepting risk inherent by participating in the bundling pilot, providers face an additional risk: program termination, should it fail to save the Medicare program money or quality of care is not maintained. To participate in the bundling pilot, institutional arrangements must be fostered between providers and suppliers—likely dependent upon the Secretary's waiving of Medicare policies. Once those policies are no longer waived, the arrangements created for the pilot must be disbanded.

Under a separate section of the new law, the Secretary is authorized to conduct Medicaid bundled payment demonstrations in up to eight states to evaluate integrated care around a hospitalization. Those eight states were not specified in the law, nor was the process by which the Secretary will choose those states.

Medicare Shared Savings Program[6]

The health care reform law's most significant new program geared toward fostering the integration of care is the voluntary Medicare Shared Savings, or Accountable Care Organization (ACO) program. Importantly, the ACO provision in the law is not a pilot, like payment bundling, but rather a permanent program under Medicare. As such, rather than the issuance of an RFP where the Secretary can choose participants, the Secretary must establish the ACO program through notice and comment rulemaking, and must allow entities that meet the requirements to participate. The proposed rule is expected to be promulgated during the Fall of 2010.

The law implements a voluntary program by January 1, 2012, to allow groups of providers to be recognized as ACOs and share in the cost savings they achieve for the Medicare program. The law allows hospitals to take the lead in their communities in developing ACOs. Hospitals in several communities across New York State are very interested in doing so. Other providers that may participate include group practice arrangements, networks of individual physician practices, partnerships or joint-venture arrangements between hospitals and practitioners, and hospitals employing practitioners. To qualify, the organization must act as the primary care provider for at least 5,000 Medicare fee-for-service beneficiaries. ACO providers must agree to participate for at least three years.

Providers in an ACO will be paid based on a global budget for the population enrolled. These providers will be allowed to share in the cost savings they achieve if the ACO meets quality performance standards established by the Secretary, and if average per capita Medicare expenditures are below a benchmark based on the claim history and characteristics of the patients assigned to the ACO. While the law does not specify the level of shared savings that this program should yield, because the program is based upon less money flowing out of the Medicare Trust Funds than would otherwise be the case under the fee-for-service program, CBO estimates the shared provider/Medicare program savings to be $4.9 billion over ten years.

The ACO model seeks to align financial incentives across the entire continuum—from primary care through

acute and post-acute care—and requires hospitals, physicians, and continuing care providers to recognize their interdependence and better coordinate and improve care through the promotion of evidence-based medicine and patient engagement. The concept shifts "performance risk" to providers from payers (in this case, Medicare) along with the potential for reward.

Similar to past capitation initiatives, it is highly dependent on detailed, patient-level data across the continuum to help estimate risk for the population to be covered. ACOs, by far the most challenging delivery system reform to implement, hold out the greatest promise for "bending the cost curve" by incentivizing care coordination.

Before the Secretary issues the proposed rule establishing the ACO program, providers and suppliers should explore the possibilities within their communities of creating an ACO, engaging in dialogue with potential partners with whom they share a patient population. Discussion should include developing a formal legal structure that would allow the organization to receive and distribute payments for shared savings to ACO participants. ACOs will also need to have in place leadership and management, including clinical and administrative systems.

As with the bundling pilot, providers and suppliers must closely monitor the Secretary's proposed rule to understand the potential protections (and the limits to those protections) she may afford in the form of the design of the program and waivers against fraud and abuse laws and regulations attached to the Medicare and Medicaid programs—which have been barriers to clinical integration. Under the law, the Secretary has the authority to waive any provisions of the False Claims Act/Anti-Kickback and Civil Monetary Penalties Act, in addition to any provisions of Title XVIII, the Medicare Title, which includes the Stark Law (self-referral) and any payment provisions and general rules for Medicare. The degree to which the Secretary will exercise this authority is unclear and will not be known until the proposed rule on the ACO program is promulgated.

Vigilance is required on the part of providers and suppliers to consider the implications of forming new relationships that may be subject to anti-trust and other laws and regulations for which the Secretary cannot issue waivers. It could be the case that providers will receive special consideration *vis-à-vis* enforcement by virtue of the fact that they participate in a program under the auspices of the federal government.

Even more so than is the case for the bundling pilot, hospitals and continuing care providers already part of an integrated system are best prepared to apply for the federal ACO program. Those providers with sophisticated electronic health record (EHR) systems and health information exchange (HIE) capabilities and linkages will have a further leg up as they are better able to collect and analyze patient data to assess risk, compared to providers without such systems and capabilities.

For many communities in New York, where the health care delivery system is fragmented and EHR adoption and HIE capabilities are in early stages, the prospect of developing successful applications to participate in the ACO program in the near term seem remote. Yet, these providers and suppliers must begin to take steps to explore potential partners, learn from those providers in the first wave of establishing ACOs, and begin to build their own ACO apparatus. As resources continue to diminish and the promise of increased revenue from expanded coverage is not yet a reality, experimenting with taking on more risk and integrating care delivery with other providers, while benefiting from shared savings, may prove to be a mechanism to survive or even flourish in an atmosphere where hospitals will likely be "doing less, with less."

The law also gives the Secretary authorization to conduct Medicaid global payment demonstrations for safety net hospitals in up to five (yet to be determined) states, and Medicaid pediatric ACO demonstrations. Providers and suppliers that participate in the Medicare ACO program are prohibited from participating in any other ACO/global budgeting program through which there is shared savings.

The Center for Medicare and Medicaid Innovation[7]

Great authority is given to the Secretary to develop and test new delivery system reform. CMI will be established within CMS by January 1, 2011, to test innovative payment and service delivery models designed to improve the coordination, quality, and efficiency of health care services provided to Medicare, Medicaid, and dual-eligible beneficiaries. As models begin to be tested, the Secretary has the authority to initially waive budget-neutrality and use the more than $10 billion allocated under the law nationwide over ten years to design, implement, and evaluate the models. An additional $10 billion is authorized for each subsequent ten-year period.

In consultation with other government agencies, the Secretary will test those models that address a defined population for which there are deficits in care, leading to poor clinical outcomes or potentially avoidable expenditures. Models specified within the law include, but are not limited to:

- patient-centered medical home models that address women's unique health care needs;
- the support of care coordination for chronically ill individuals at high risk for hospitalization through a health information technology-enabled provider

network that includes care coordinators, a chronic disease registry, and home telehealth technology;

- allowing states to test and evaluate fully integrating care for dual-eligibles in the state, including management and oversight of all Medicare and Medicaid funds;
- allowing states to test systems of all-payer payment reform for the medical care of residents of the state, including dual-eligibles; and
- establishing and making comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other providers that deliver a full spectrum of integrated and comprehensive health care services to Medicare, Medicaid, or dual-eligibles, while incorporating innovative methods for the clinical training of future health care professionals.

A model under testing can be terminated or modified by the Secretary at any time should she and the CMS Chief Actuary determine it will not save money, or maintain or increase the quality of care delivered. The Secretary must evaluate all models being testing and make such evaluation public.

The Secretary may, through rulemaking, expand—including on a nationwide basis—the duration and scope of models if she determines as an expanded program they reduce Medicare and/or Medicaid spending without reducing the quality of care or would improve the quality of care without increasing spending. Further, the CMS Chief Actuary must certify that such expansion would "reduce (or not result in any increase in) net program spending.…" That is, of her own authority and without the need to seek additional authority from Congress, the Secretary can expand new delivery system reform pilot programs to the national stage. Innovation can occur and expand more rapidly than CMS has ever been able to accomplish.

It is clear from the language of the law that while not a requirement to reduce savings, models to be chosen for tested and national expansion that are expected or can be certified to reduce spending will be given preference.

While the new law allows for certain laws and regulations, including all of Titles XI and XVIII, along with portions of the Title XVIX, to be waived by the Secretary only during the testing phase, once the model testing is done and the model is expanded, those specific protections are nullified. It is likely that the Secretary will need to seek additional or extended authority through legislation to allow for the tested models to persist and be expanded.

As with other pilot programs, providers run the risk of modifying or establishing institutional arrangements under the environment of waived rules for the testing phase, only for those protections to be lost once the testing is over. These providers may be forced to seek assistance from Congress in continuing the new institutional arrangements that characterize the model.

Providers willing to accept risk and experiment with innovative models to improve care coordination and delivery that require initial start-up capital should consider developing a proposal for CMI. As with other delivery system reform, providers must await guidance from the Secretary as to what specific parameters must be met to apply. Given the early start date by which CMI must be established (January 1, 2011), the wait will not be long.

Implementing Health Care Reform with Less: Medicare and Medicaid Cuts to Hospitals and Continuing Care Providers

Shared Responsibility

Throughout the legislative process, the national hospital community and hospitals in New York State supported the concept of shared responsibility where all stakeholders—government, providers, public and private payers, employers, and consumers—are involved in the development of health care reform and assume a level of accountability in its success. It was ultimately through shared responsibility that the new law and its expansion of health insurance coverage were possible.

Given the already fragile financial condition of New York's providers, where bottom-line margins in 2008 were negative 2.2%, the level of reductions to New York hospitals and hospital-based health systems—$13.5 billion over ten years—raises serious concern about the capacity of many hospitals to successfully implement health care reform and serve their communities. The majority of cuts ($11.5 billion) come from reductions in Medicare reimbursement through decreases in inflationary updates and Disproportionate Share Hospital (DSH) payments. Given that on average, 45% of inpatient days in New York hospitals are Medicare days, any Medicare reimbursement reduction has a significant impact on the overall financial health of the state's hospitals. This is especially problematic layered on top of the six New York State budget reductions in Medicaid spending over the last three years.

Hospitals and health systems across New York already are cutting services, reducing staff, and scaling back or cancelling projects, including technological enhancements. There is a tipping point between how far reimbursement can be reduced and the continued capacity for hospitals to invest in the staff, programs, services, and infrastructure necessary to provide the quality care every community deserves. New York hospitals are at that point now. While the hospital community will experience increased revenue as coverage expansion begins to take hold in 2014, the reductions start right away and

many hospitals expect the cuts to outstrip the value of any increases in revenue.

Annual Medicare Marketbasket Updates[8]

Under the new law, Medicare inflationary (market-basket) adjustments for hospitals and continuing care providers will be reduced starting April 2010 and continuing into perpetuity. The impact over the next ten years alone will be a $157 billion reduction nationwide and $7.6 billion to New York hospital and hospital-based continuing care providers. The policy of cuts was made permanent out of a political will to show deficit reduction over a 20-year period. The hospital community fought in vain for this provision to sunset and for a floor to be provided such that no update could fall below zero. Those provisions were not achieved.

Across the continuum of care—inpatient hospitals, inpatient rehabilitation hospitals, nursing facilities, home health agencies, and hospices—Medicare payments to New York hospitals, health systems, and continuing care providers often do not cover the cost of providing care, causing negative Medicare operating margins.

While not focused on as much as the critical Medicare revenue streams of Disproportionate Share Hospital (DSH) payments or of Graduate Medical Education policies, for understandable reasons, the Medicare update factor is a significant revenue stream, the reduction of which will be felt by virtually all hospitals in New York beginning this year.

Disproportionate Share Hospital Payment Reductions[9]

The Medicare and Medicaid DSH programs provide financial support to hospitals throughout New York State, enabling them to care for our state's most vulnerable while supporting specialty services that would otherwise be significantly less accessible to all. DSH payments help cover not only losses due to uncompensated care, but also the additional costs incurred in serving poor and disadvantaged populations in rural and urban areas. The Medicaid DSH program supports a broad array of services for Medicaid, uninsured, and underinsured children and adults. Low-income and disadvantaged populations are more likely to have chronic conditions or other complicating factors that increase the cost of providing care. DSH payments help cover the costs of providing that care.

The health care reform law will reduce DSH payments to hospitals nationwide by $36 billion over ten years, beginning in 2014; New York hospitals will experience an estimated $4.5 billion in reductions. The reform law maintains current DSH payments levels until coverage expansion begins to take hold. Vigilance must be maintained to ensure that the level of reductions are such that safety net hospitals are adequately supported to provide comprehensive care to their most vulnerable patient populations and to continue to provide specialty services for all in their communities

Even if the coverage expansions projected under the new law are achieved—covering 94% of all American citizens—some populations will remain uncovered or underinsured, particularly in communities with a significant undocumented population, and hospitals will be asked to bear the burden of their health care and essential community services.

Insurance Market Reform[10]

Health insurance market reform provisions are a core component of the new law and integral to coverage expansion. The new and significant changes to insurance industry practices affect both the individual and small group markets. Taken together, these provisions aim to improve the affordability of health insurance, extend coverage, and close coverage exclusions that have bedeviled consumers and small employers for decades.

Some of the reform provisions are effective almost immediately; others will be phased in over the next several years in conjunction with coverage expansion. Health insurance market reform addresses three key areas:

- financial issues related to providing access to coverage, such as requiring plans to eliminate lifetime, annual or unreasonable limits on benefits;
- new claims processing and reporting standards that require insurers to meet minimum medical loss ratios and report annually to HHS on measures such as the percent of total premium revenue spent on provider reimbursement; and
- annual review of unreasonable premium increases before increases are implemented.

In New York, the provider community has fought for and obtained a number of the insurance market reform provisions within these three categories. Providers achieved breakthroughs on authorization laws, coordination of benefit regulations, external appeals rights, and claims submission standards. Providers have consciously secured these advances in a manner that avoids unintended consequences of forcing premiums up or reducing the ability of insurers to give providers rate increases when they are needed and justified.

The central question for providers with federal health insurance reform implementation will be whether the market reform can be achieved without significant increases in premiums to large segments of the market, and without adversely affecting the ability of insurers to have flexibility in product design, and to give providers needed rate increases.

Federal Insurance Market Reform Timeline	
Reform Action	**When It Occurs**
Health plans must **eliminate lifetime, annual, or unreasonable limits on coverage;** the law does not prevent a plan that does not provide essential health benefits, as defined by the Secretary, from placing per-beneficiary limits on specific covered benefits.	October 2010
A plan that provides **dependent coverage for children** must continue to offer it until the child turns 26, as long as the child is not eligible to enroll in any other employer-sponsored health plan. New York's age extender law, which provides coverage to age 29, uses Consolidated Omnibus Budget Reconciliation Act (COBRA) rates as the amount to be paid when a child stays on the family coverage. The federal standard may solve the New York cost problem and should pre-empt New York's law, but there is uncertainty about how the premium costs will be distributed.	October 2010
The **ban on retroactively canceling health coverage** will be extended to employer-based group policies, except in the case of fraud.	October 2010
The **minimum required medical loss ratio** (MLR) for the group market will be 85%; 80% for the individual market. State law that requires a higher MLR will preempt this new federal standard, unless the Secretary determines the state's minimum MLR may destabilize the individual market. Beginning in 2011, health plans that spend less than these thresholds on care will be compelled to provide refunds to members. Each year, a health plan must submit a report detailing the percent of total premium revenue that is spent on provider reimbursement, activities that improve health care quality, and all other non-claim costs, excluding taxes. The report will be made public on the HHS Web site. Beginning in 2014, MLRS will be based on the average of the premiums used to reimburse providers for the health care services for each of the previous three years.	October 2010
Plans must have an effective **process for appealing** coverage determinations and claims. Plans must include consumer protections set forth in the Uniform Review Model Act, which establishes standardized protocols for external review to ensure that covered people have the opportunity for an independent review of an adverse determination or final adverse determination regarding benefits for specific procedures or services.	October 2010
The Secretary, in cooperation with states, will establish a process for the **annual review of unreasonable premium increases**. It will require health plans to justify an unreasonable premium increase before implementing it. The plan's justification will be made public on the HHS Web site.	October 2010
A plan must provide **coverage without cost-sharing requirements for certain preventive care services.**	October 2010
Plans **may not discriminate in favor of highly compensated employee**s in terms of eligibility or level of benefits under a plan.	October 2010
The Secretary and states will begin **monitoring premium increases** offered through and outside of an exchange. When determining whether to offer a health plan in the large group market through an exchange, the state must take into account excess premium growth outside of the exchange compared to the rate of premium growth inside the exchange.	2014
Plans must provide a **summary explanation of benefits** and coverage to participants prior to enrollment. The Secretary will provide standards for developing the summary by 2011.	2013
The Secretary will develop reporting requirements for use by health plans aimed at **improving health outcomes.** These reporting requirements may affect provider reimbursement. The Secretary will promulgate regulations that will provide criteria for determining a reimbursement structure aimed at improving health outcomes.	By 2012
Health plans that offer coverage **must accept every employer and individual that applies for coverage.** The plan must also renew or continue to offer coverage for all members.	2014
Plans may not impose **any waiting period** in excess of 90 days.	2014
Plans may not establish rules for eligibility to enroll based on the **individual's health status.**	2014
Plans cannot deny participation of a qualified individual in a **clinical trial**, deny coverage of routine costs in connection with the clinical trial, or discriminate on the basis of participation in a clinical trial.	2014
Premium rates may only vary by whether the plan covers an individual or family; rating area (to be established by the state); age—may not vary more than 3:1 for adults; or tobacco use—may not vary more than 15:1.	2014
Plans must limit **cost-sharing amounts** to the limits applicable to high-deductible health plans. Group health plans cannot have deductibles that exceed $2,000 for single coverage or $4,000 for other coverage. These amounts are subject to cost-of-living adjustments after 2014.	2014

Potential Unintended Consequences of Key Insurance Market Reform

The insurance market reform provisions are based on fundamental expectations and assumptions. If these premises are flawed, some or all of the reform may not work.

Providing Access to Coverage

A key unanswered question is whether the incentives and penalties in the new law will succeed in expanding coverage to anticipated levels.

For the coverage mandates to work, broad participation is necessary or costs and premiums will jump. Young and healthy people need to be in the insurance pools to contain premium costs. Because providers rely so heavily—despite frequent disagreements and skirmishes—on their relationships with health insurers, the provider world becomes more complex if premiums for many purchasers in the new marketplace increase significantly.

Many of the new coverage mandates address what could broadly be described as underwriting concerns. Providers believe they are improperly underpaid because one of two things has happened:

- An insurer has found a way to re-underwrite its coverage or its contract with a provider to redefine an area of exposure. We consider this type of action a "front end" solution.
- The insurer could challenge the claim for services based on utilization or authorization standards or claims processing and payment standards, a "back end" solution.

As the new mandates transform insurance underwriting and the plans cope with guaranteed issue, lifetime benefit caps, and elimination of pre-existing condition coverage exclusion, we could see an industry spike in back end solutions with utilization reviews, audits, and transaction related disputes.

As quality initiatives are linked to all aspects of reimbursement, and as health plans struggle with coverage mandates, we could see insurers squeeze providers harder at the back end.

Should this occur, the $465 billion that the American Hospital Association reports is spent annually on the administration of claims may grow.

Secretary's Authority to Review Plan Premium Increases

The Secretary, working with the states, will begin to review proposed plan premium increases. This issue became a lightning rod for reform before passage of the Act when a large national plan proposed huge premium increases in California. This spurred renewed focus on Capitol Hill on out-of-control insurer profits—because plans appeared to have no intention of reinvesting profits back in health care infrastructure or in premium rebates to overpaying consumers.

But premium increases are only a part of the story. As Medicare and Medicaid reimbursement shrinks, the commercial insurance market has been at least somewhat predictable for the provider community. A possible negative consequence of the Secretary's authority to approve premium increases could be that plan-provider negotiations become even more intractable. Bureaucratic delays or political forces could stand in the way of premium increases to a plan, with the result that providers cannot, in turn, negotiate increased payments from plans.

Conclusion

Over the next several years, bending the cost curve and implementing near-universal coverage and comprehensive delivery system reform offers great promise—and hazards—for providers as pressure mounts to move the health care delivery system away from fee-for-service and toward a patient-centric, integrated model.

As hospitals and continuing care providers implement this reform from different starting places on the integration and risk acceptance continuum while facing Medicare and Medicaid payment reductions, they will vary in their capacity to succeed. Insurance market reform, though badly needed, may yield some unintended and negative consequences for providers.

Undoubtedly, as with any legislation of this magnitude, modifications and corrections to the law will need to be made over time to improve the design of the delivery system reform, ease the burden of cuts on providers, and modify insurance reform to address negative consequences such reform may have on providers.

Endnotes

1. The Patient Protection and Affordable Care Act (pub. L. 111-148) (PPACA) and the Health Care and Education Reconciliation Affordability Act of 2010 (pub. L. 111-152) (HCERAA).
2. Impact analysis of the major Medicare and Medicaid provisions in the federal health care reform law affecting New York hospital and hospital-based continuing care providers performed by the Healthcare Association of New York State.
3. PPACA sections 3001, 3006, and 10326.
4. PPACA sections 3025 and 10309.
5. PPACA sections 3023 and 10308.
6. PPACA sections 3022 and 10307.
7. PPACA sections 3021 and 10306.
8. PPACA sections 3401 and 10319; HCEARA section 1105.
9. PPACA sections 2551 and 3133; HCEARA sections 1104 and 1203.
10. PPACA sections 1001, 1002, 1003, 1005, 1201, 1251–1253, and 1301-1304.

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Congress Acts on the Stark Disclosure Dilemma: Federal Health Reform Authorizes New Stark Self-Disclosure Protocol

By Robert D. Belfort and Emily Lee

On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act, H.R. 3590 ("PPACA"). In addition to enacting a myriad of health care reform provisions, Section 6409 of the PPACA requires the Centers for Medicare and Medicaid Services ("CMS") to create a self-disclosure protocol under which health care providers may voluntarily report potential Stark Law violations. This is a welcome development for hospitals and other health care providers that discover unintentional or "technical" violations of Stark and face potentially massive exposure to liability for such violations without any clear mechanism to fairly resolve these claims.

"Because Stark is a strict liability statute, failure to comply with its many technical requirements can result in significant penalties regardless of a provider's lack of intent to violate the statute."

Background

Stark prohibits physicians from referring Medicare patients for certain designated health services ("DHS") to any entity with which the referring physician (or an immediate family member) has any direct or indirect financial relationship, unless an exception applies. 42 U.S.C. § 1395nn(a)(1)(A). In addition, Stark prohibits entities from billing Medicare for services provided pursuant to a prohibited referral. Stark regulations further require the entity that collects payment for DHS performed in connection with a prohibited referral to refund all collected amounts on a timely basis. 42 C.F.R. § 411.353(d).

Because Stark is a strict liability statute, failure to comply with its many technical requirements can result in significant penalties regardless of a provider's lack of intent to violate the statute. For example, if a lease agreement between a hospital and a physician expires and is not renewed within six months of the expiration date, all referrals of Medicare patients by the physician to the hospital after such period violate Stark. The hospital may not have learned of this lapse in paperwork until years have passed. By then, the hospital may have received payment of millions of dollars for services attributable to referrals from that physician, all of which are subject to recoupment by the government. This liability attaches even if the physician continued to pay rent that was consistent with fair market value.

Reporting such technical violations to CMS has been problematic for providers because CMS has historically taken the position that it does not have the authority to negotiate a settlement less than the full value of the Medicare billings resulting from the tainted referrals.

Use of OIG Self-Disclosure Protocol

In April 2006, the U.S. Department of Health and Human Services Office of Inspector General ("OIG") announced an initiative to promote disclosure of potential Stark and/or Anti-Kickback Law violations under the OIG's Self-Disclosure Protocol ("SDP"). See OIG Open Letter to Health Care Providers (April 24, 2006). In the letter, OIG indicated that monetary settlements in SDP cases would generally be for amounts near the lower end of the damages spectrum. To avoid the problems raised by disclosure to CMS, many providers opted to disclose technical Stark violations through the SDP, as such disclosures could result in settlements for less than the full value of Medicare billings and protection from potential *qui tam* lawsuits under the False Claims Act ("FCA").

However, in March 2009, OIG announced that it would no longer accept disclosure of a Stark violation in the absence of a "colorable" violation of the Anti-Kickback Statute. See OIG Open Letter to Health Care Providers (March 24, 2009). Further, OIG announced that it would accept only matters involving a settlement of at least $50,000. OIG indicated that its decision to narrow the scope of the SDP was based partly on lack of resources.

The OIG's exclusion of Stark Law violations from the SDP left health care providers with limited and unappealing options for addressing inadvertent Stark violations. Those options consisted of reporting to CMS, the Medicare payment contractors (fiscal intermediaries and carriers), or to the U.S. Department of Justice (through the local U.S. Attorney's Office). None of those approaches gave providers comfort that they could negotiate a reasonable settlement commensurate with the nature of the violation.

To complicate matters, the Fraud Enforcement and Recovery Act of 2009 ("FERA") amended the FCA in a

manner that increased the risk of FCA exposure for health care providers that discover technical Stark violations. Post-FERA, the FCA imposes civil penalties of up to $11,000 for each claim—plus treble damages—on any person who "knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government," even in the absence of an affirmative false statement. 31 U.S.C. § 3729(a)(1)(G). Thus, a provider that discovers an inadvertent Stark Law violation, and does not repay Medicare for payment collected for DHS performed under a prohibited referral, theoretically could be exposed to massive penalties under the FCA for knowingly avoiding an "obligation" to repay the government.

Creation of a Stark Self-Referral Disclosure Protocol under the PPACA

Congress has taken an important step in addressing the current predicament faced by health care providers by establishing a new process for reporting Stark violations:

- ***Establishment of an SRDP.*** Section 6409 of the PPACA requires the U.S. Department of Health and Human Services ("HHS") to work with OIG to establish a protocol for self-disclosure of actual and potential Stark violations ("SRDP") by September 23, 2010. The SRDP must include direction to health care providers on i) a specific person, official, or office to whom such disclosures shall be made; and ii) instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.
- ***CMS authority to negotiate settlements of Stark violations.*** Significantly, Section 6409 expressly authorizes HHS to reduce amounts due and owing for Stark Law violations. In determining amounts owed for a violation, HHS may consider factors such as i) the timeliness of the self-disclosure; ii) the provider's cooperation in providing more information related to the disclosure; iii) the nature and extent of the improper or illegal practice; and iv) any other factors HHS considers appropriate. This is an important development as it gives CMS explicit authority to compromise repayment amounts to less than the full value of Medicare billings at issue.
- ***Relationship to Stark Advisory Opinion Process.*** Section 6409 also clarifies that the SRDP process is to be separate from the Stark advisory opinion process established under 42 U.S.C. § 1395nn(g).
- ***Publication of SRDP information.*** HHS must issue instructions on how to disclose actual or potential violations pursuant to an SRDP on CMS's website.
- ***Report to Congress.*** No later than 18 months after the date on which the SRDP protocol is established, HHS must provide Congress with a report on i) the number of health care providers making disclosures pursuant to the SRDP; ii) the amounts collected pursuant to the SRDP; iii) the types of violations reported under the SRDP; and iv) such other information as may be necessary to evaluate the impact of the SRDP legislation.

There are several issues that are not addressed in the legislation. For one, it is unclear how the SRDP will relate to OIG's SDP when the conduct at issue potentially implicates both the Stark and Anti-Kickback Laws. Moreover, the legislation does not address how disclosure through the SRDP will affect the operation of a separate provision in the PPACA that requires the reporting and returning of an identified Medicare overpayment by a specified deadline. An earlier version of the legislation passed by the House included a provision providing that disclosure through SRDP extended the deadline for return of an overpayment under that section. Nonetheless, the legislation is a favorable development for hospitals and other health care entities that face enormous potential exposure to liability for largely technical Stark violations, and should provide a more equitable and reasonable means for resolving provider liability for such violations.

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This article appeared previously on the Manatt, Phelps and Phillips website.

The Family Health Care Decisions Act: A Summary of Key Provisions

By Robert N. Swidler

On March 16, 2010, Governor Paterson signed into law the Family Health Care Decisions Act (FHCDA).[1] The FHCDA establishes the authority of a patient's family member or close friend to make medical treatment decisions for the patient in the event the patient lacks capacity to make such decisions personally, and did not previously make such decisions or appoint a health care agent.

Key provisions of the FHCDA are summarized below. However, the new law is detailed, and this summary does not cover all its provisions.

In sum, the FHCDA:

Applicability

Applies to decisions for incapable patients in general hospitals and residential health care facilities (nursing homes).[2] The term "hospital" is used to apply to both those settings.[3]

- Does not apply to decisions for incapable patients:
  - who have a health care agent;[4]
  - who have a court-appointed guardian under SCPA 1750-b;[5]
  - for whom decisions about life-sustaining treatment may be made by a familiy member or close friend under SCPA 1750-b;[6]
  - for whom treatment decisions may be made pursuant to OMH or OMRDD surrogate decisionmaking regulations.[7]

Determining Incapacity

- Sets forth a hospital-based process to determine that a patient lacks decisional capacity for purposes of the FHCDA.[8]
- Requires special credentials for professionals for determining that the patient lacks capacity as a result of mental retardation or mental illness.[9]
- Requires that the patient and prospective surrogate be informed of the determination of incapacity.[10]
- Requires additional notifications for patients from mental hygiene facilities.[11]
- Provides that if the patient objects to the determination of incapacity, or the choice of surrogate, or the surrogate's decision, the patient's objection prevails unless a court find that the patient lacks capacity, or another legal basis exists for overriding the patient's decision.[12]

Decisions for Adult Patients by Surrogates

- Sets forth, in order of priority, the persons who may act as a surrogate decisionmaker for the incapable patient, i.e.:[13]
  - an MHL Article 81 court-appointed guardian (if there is one);
  - the spouse or domestic partner (as defined in the FHCDA);
  - an adult child;
  - a parent;
  - a brother or sister;
  - a close friend.
- Grants the surrogate authority to make all health care decisions for the patient that the adult patient could make for himself or herself, subject to certain standards and limitations.[14]
- Provides that a surrogate's consent is not required if the patient already made a decision about the proposed health care, expressed orally or in writing or, with respect to a decision to withdraw or withhold life-sustaining treatment expressed either orally during hospitalization in the presence of two witnesses or in writing.[15]
- Requires the surrogate to decide about treatment based on the patient's wishes, including the patient's religious and moral beliefs, or, if the patient's wishes are not reasonably known and cannot with reasonable diligence be ascertained, based on the patient's best interests.[16]
- Authorizes surrogate decisions to withhold or withdraw life-sustaining treatment if the treatment:
  - would be an extraordinary burden to the patient and the patient is terminally or permanently unconscious, or
  - if the patient has an irreversible or incurable condition and the treatment would involve such pain, suffering or other burden that it would

reasonably be deemed inhumane or excessively burdensome under the circumstances.[17]

- Inasmuch as the definition of life-sustaining treatment includes decisions about resuscitation, this standard would apply to a surrogate decision to enter a DNR order as well.[18]

Decisions for Minor Patients

- Authorizes the parent or guardian of a minor patient to decide about life-sustaining treatment, in accord with the same standards that apply to surrogate decisions for adults.[19]
- Requires the parent or guardian to make the decision in accordance with the minor's best interests, taking into account the minor's wishes as appropriate under the circumstances.[20]
- If the attending physician determines that the minor has the capacity to decide about life-sustaining treatment, requires the minor's consent to withhold or to stop treatment.[21]
- If there is another parent who is unaware of the decision, requires an attempt to inform such parent of the decision.[22]
- Allows a physician to accept a life-sustaining treatment decision by an emancipated minor without parental consent, although a decision by the minor to forgo such treatment requires ethics review committee approval.[23]

Decisions for Adult Patients Without Surrogates

- Establishes a procedure for making health care decisions, other than life-sustaining treatment decisions, for adult patients who have lost decision-making capacity and have no available family member or friend to act as a surrogate.[24]
- Requires hospitals, after a patient is admitted, to determine if the patient has a health care agent, guardian, or a person who can serve as the patient's surrogate. If the patient has no such person, and lacks capacity, the hospital must identify, to the extent practical, the patient's wishes and preferences about pending health care decisions.[25]
- Authorizes the attending physician to decide about routine medical treatment for patients without surrogates.[26]
- For decisions about major medical treatment, the attending physician must consult with other health care professionals directly involved with the patient's care and a second physician selected by the hospital or nursing home must concur in the decision.[27]
- A decision to withdraw or withhold life-sustaining treatment can be made either (a) by a court, in accordance with the FHCDA surrogate decisionmaking standards, or (b) if the attending physician and a second physician determine that the treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided, and the provision of the treatment would violate accepted medical standards.[28]

Other FHCDA Provisions

- Requires hospitals and nursing homes to establish or participate in an ethics review committee that meets certain standards (e.g., multidisciplinary membership).[29]
- The committee would provide advice upon request or in the event of disputes, and review certain sensitive surrogate decisions.[30]
- Sets forth the right of private hospitals and individual health care providers to refuse, on grounds of moral or religious conscience, to honor health care decisions made pursuant to the FHCDA, subject to limits and requirements (e.g., the facility must notify patients of its policy prior to admission, and promptly transfer responsibility for the patient to another health care professional willing to honor the decision.)[31]
- Protects surrogates, health care providers and ethics committee members from civil and criminal liability for acts performed in good faith pursuant to the FHCDA.[32]
- Provides that liability for the cost of health care provided to an adult patient under the FHCDA is the same as if the patient had consented to treatment.[33]
- Establishes that the FHCDA does not:
  - expand or diminish any authority an individual may have to express health care decisions for himself or herself;[34]
  - affect existing law concerning implied consent to health care in an emergency;[35]
  - permit or promote suicide, assisted suicide, or euthanasia;[36]
  - diminish the duty of parents to consent to treatment for minors.[37]
- Provides that a hospital or attending physician that refuses to honor a health care decision made by a surrogate in accord with the standards set forth in the FHCDA is not be entitled to compensation for treatment provided without the surrogate's consent, except under specified circumstances.[38]

Resuscitation-related Provisions

- Eliminates much of New York's DNR Law as applied to hospitals, and provides for DNR decisionmaking in hospitals in accordance with the standards and procedures in the FHCDA.[39]
- Creates a new PHL Article 29-CCC as a place to retain (with some modifications) existing provisions on nonhospital DNR orders.[40]
- Obligates home care agency staff and hospice staff to honor nonhospital DNR orders (previously, nonhospital DNR orders were directed only to emergency medical services and hospital personnel).[41]
- Renames the former DNR law, PHL Article 29-B, as "Orders Not to Resuscitate for Residents of Mental Hygiene Facilities" in order to preserve existing authorization for and rules regarding DNR orders in those settings.[42]

Health Care Proxy Law Amendments

- Amends the Health Care Proxy Law:
  - to require provider, when an agent directs the provision of life-sustaining treatment, either to provide the treatment, transfer the patient, or seek judicial review;[43]
  - to adopt the FHCDA provisions regarding institutional and health care provider conscience provisions.[44]

Conforming Amendments to MHL Article 81 and the Health Care Decisions Act (SCPA 1750-b)

- Authorizes an MHL Article 81 guardian of the person to act as a surrogate under the FHCDA for decisions in hospitals.[45]
- Repeals provisions in MHL Article 81 that restrict the authority of a guardian to make life-sustaining treatment decisions.[46]
- Amends the Health Care Decisions Act for Mentally Retarded Persons (SCPA 1750-b) to insert a definition of "life-sustaining treatment" (because previously it referred to a definition in MHL Article 81 which will be repealed).[47]
- Amends the Health Care Decisions Act to allow the Willowbrook Consumer Advisory Board to act as the HCDA guardian for class members.[48]

Task Force Special Committees

- Directs the NYS Task Force on Life and the Law to create a special committee, with half of its members appointed by OMRDD and OMH, to provide advice on standards and procedures for surrogate decisionmaking for persons with MR/DD, and persons in mental health facilities.[49]
- Directs the NYS Task Force on Life and the Law to make recommendations on extending FHCDA decisionmaking standards and procedures to other settngs, such as physicians' offices and home care.[50]

Effective Date

- Hospitals are required to implement the FHCDA by June 1, 2010, but effective immediately hospitals are are *permitted* to adopt and follow policies that are consistent with the FHCDA standards and procedures.[51]

Endnotes

1. Chapter 8, Laws of 2010, adding N.Y. Public Health Law Article 29-CC ("The Family Health Care Decisions Act") and amending various other laws.
2. N.Y. Public Health Law §2994-b.1.
3. *Id.*, §2994-a.16.
4. *Id.*, §2994-b.2.
5. *Id.*, §2994-b.3(a).
6. *Id.*, §2994-b.3(b).
7. *Id.*, §2994-b.3(c).
8. *Id.*, §2994-c.
9. *Id.*, §2994-c.3(c).
10. *Id.*, §2994-c.4(a), (b).
11. *Id.*, §2994-c.4(c).
12. *Id.*, §2994-c.6.
13. *Id.*, §2994-d.1.
14. *Id.*, §2994-d.3(i).
15. *Id.*, §2994-d.3(ii).
16. *Id.*, §2994-d.4.
17. *Id.*, §2994-d.5.
18. *Id.*, §2994-a.19.
19. *Id.*, §2994-e.1.
20. *Id.*, §2994-e.2(a).
21. *Id.*, §2994-e.2(b).
22. *Id.*, §2994-e.2(c).
23. *Id.*, §2994-e.3.
24. *Id.*, §2994-g.
25. *Id.*, §2994-g.1.
26. *Id.*, §2994-g.3.
27. *Id.*, §2994-g.4.
28. *Id.*, §2994-g.5.
29. *Id.*, §2994-m.
30. *Id.*, §2994-m.2.
31. *Id.*, §2994-n.
32. *Id.*, §2994-o.
33. *Id.*, §2994-p.

34. *Id.*, §2994-q.1.
35. *Id.*, §2994-q.2.
36. *Id.*, §2994-q.3.
37. *Id.*, §2994-q.4.
38. *Id.*, §2994-s.
39. See Chapter 8, Laws of 2010, §4, which amends N.Y. Public Health Law Article 29-B the DNR law to make it applicable only to mental hygiene facilites. See also new N.Y. Public Health Law §2994-a.19, which defines "life-sustaining treatment" to include cardiopulmonary resuscitation. See also FHCDA §4, which amends N.Y. Public Health Law Article 29-B (the DNR law) to make it applicable only to mental hygiene facilities.
40. Chapter 8, Laws of 2010, §2, adding N.Y. Public Health Law Article 29-CCC Nonhospital Orders Not to Resuscitate.
41. N.Y. Public Health Law §2994-ee.
42. *See* note 39.
43. Chapter 8, Laws of 2010, §23. amending N.Y. Public Health Law §2984.3.
44. Chapter 8, Laws of 2010, §23, adding N.Y. Public Health Law §2984.5.
45. Chapter 8, Laws of 2010, §25, amending N.Y. Mental Health Law §81.22.8.
46. Chapter 8, Laws of 2010, §25, repealing N.Y. Mental Health Law §81.22.9(e).
47. Chapter 8, Laws of 2010, §27, amending N.Y. Surrogate's Court Procedure Act §1750-b.
48. Chapter 8, Laws of 2010, §27, amending N.Y. Surrogate's Court Procedure Act §1750-b.
49. Chapter 8, Laws of 2010, §28.1.
50. Chapter 8, Laws of 2010, §28.2.
51. Chapter 8, Laws of 2010, §29.

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The Out-of-Network Benefit Dilemma: A Crisis for Health Care Providers and Their Patients

By James G. Fouassier

Consumer and personal bankruptcies are at an all time high. The statistics tell us that the biggest cause for individual bankruptcies is medical debt. Yet the vast majority of Americans are covered by some kind of health insurance or benefits from some form of health care plan. How can this be? Experts tell us the reason is that too many of us are "underinsured." We have what appears to be adequate insurance or health plan coverage but when we need it we find out that too much of the cost of our care is not paid or reimbursed by our health coverage plan and we are personally accountable for large balances.

"Consumer and personal bankruptcies are at an all time high. The statistics tell us that the biggest cause for individual bankruptcies is medical debt. Yet the vast majority of Americans are covered by some kind of health insurance.… How can this be?"

One of the contributors to this growing problem is the "out-of-network benefit dilemma." This is the story of Jack Foster, a middle class family man whose fictional experience with the out-of-network benefit dilemma is all too real for many of us.

Jack Foster remembers the day he first hurt his neck. Resisting the teasing of his younger colleagues he was cajoled into a lunchtime game of hoops. A sudden twist and turn of his head sent a sharp pain down his cervical column. With analgesics and ice the pain subsided to a throb but, after a few weeks with no real relief, he decided that he must have done some damage. His primary care physician referred him to an orthopedic surgeon for evaluation.

Fortunately for Jack, his employer sponsored health plan covered the surgeon's professional services. Jack liked the "PPO" plan, which allowed him to choose from a large panel of participating providers.[1] What he did not like was the bigger share of the cost of the coverage being pushed back on him and his co-workers every year or so. His percentage share of the premiums had increased dramatically; now he has a larger deductible and copayment responsibility and, even worse, some of the coverage for certain benefits now had dollar limits. Jack could have switched to an "HMO"[2] but he wanted the extra protection the PPO's "out-of network" option allowed in the event that he or a family member needed to use a provider not under contract with a health plan HMO to accept previously negotiated rates for covered services. So Jack paid the premium difference out of his own pocket.

A series of conservative treatments was ineffective and Jack had to undergo day surgery. At registration he was offered a half dozen "blank" forms to sign, both for the hospital and for the surgeon.[3] Included was a standard form of an "assignment of benefits," in which Jack legally gave over to the surgical group the right to bill his health plan for the costs of the services and treatment. Since the hospital and the doctors both were "in network" with Jack's plan, meaning that they had to accept whatever the plan paid (less the usual, relatively modest copayment and annual deductible), the assignment was not really necessary but there always was one included among the pile of papers a patient was asked to sign.[4] Somewhere else in the pile, he later recalls, was something about having to pay personally if any service later was determined to be "non-covered" or excluded from his plan benefits, and also something about how he personally would be responsible for anything his plan did not pay. No one explained anything to him about fees, costs, insurance coverage or anything having to do with expenses or what he might have to pay "out of pocket." Jack was not given a copy of the papers he signed. He paid his standard hospital copayment but nothing for the surgeon. The next morning he came in for the procedure; it went well.

Jack never saw a claim, statement or billing. He did receive an "explanations of benefits," known as an "EOB," from his plan, which he barely understood, telling him what the plan was billed and what it paid to the hospital and the surgeon. He was surprised at how much more his providers billed the doctors and the hospital than they actually were paid, but since they accepted what they were paid without asking him to pay any more himself he filed away the "EOBs" and promptly forgot about the whole thing, concentrating instead on his physical therapy.

Three years later, while emptying out his late mother's apartment, Jack somehow twisted his neck the wrong way and reinjured himself. Once again his family physician diagnosed possible cervical spine damage and sent him back to his surgeon. Once again conservative treatment was unsuccessful and surgery was required. This time it would be a more complex and lengthy procedure requiring an inpatient admission and a stay of several days. Just like the first time, Jack dutifully reported to presurgical registration, filled out all the forms in blank and paid his hospital copayment, but again was given no cop-

ies and told nothing about any financial responsibility. This surgery also went well, and in three days Jack was discharged to follow-up care in his surgeon's office.

About a year before Jack's second surgery his orthopedic surgeon, Dr. Jones, and the other physicians in his practice group engaged in their bi-annual ritual of negotiating a new managed care agreement with the insurance company that administered Jack's plan. Try as they might, there just was no way the doctors could agree to accept the rates the plan proposed, especially when linked in with a variety of new technical requirements that virtually guaranteed an increase in payment denials and short paid claims. Frankly the doctors were tired of arguing with the plan over whether expensive treatments and procedures should be covered. So with reluctance and no small degree of trepidation Dr. Jones and his group terminated their contract with the health plan. Henceforth the practice group would be "out-of-network." The group no longer had to follow all the technical administrative claims requirements which the plan mandated, and instead could just send the plan—or the patient—a bill for the full amount of the services based on the doctors' actual retail charges. As a courtesy to its out-of-network patients the physician group still would notify the plan in advance and secure authorizations when required, to be sure the service would be "covered" and the plan would pay something. No longer would the group benefit, however, from plan "steering" of members, so it anticipated a drop in its volume of business. Also, whatever the plan paid now would be paid directly to its members and not to the doctors, so the group often would find itself having to chase its own patients to recover the payments.[5]

When the group decided to terminate its agreement with the insurance plan a minor disagreement broke out among the doctors over just what to tell the patients. Ms. Lowery, the office manager, thought that sending a letter to current patients covered by the plan, explaining what happened, might be a good idea but several partners, fearing a loss of business as patients moved to "in network" providers, quietly discouraged her and the idea never came up again.

Jack's health plan administrator received the bills for the second surgery in due course. The bills set out the "actual charges" for the services rendered by the hospital and the surgeon.[6] In both cases the plan ignored the actual charges. The hospital still was "in network" with the plan under a managed care contract which it recently renewed and was bound by its contract to accept a fixed sum for the procedure (which is called a "case rate"), so the actual amount it billed the plan was irrelevant. The surgeon's bill was another matter altogether. The surgeon's actual billed charges were $67,450. Jack's out-of-network benefit design required the plan to pay 80% of the "usual and customary" charge (sometimes known as the "usual, customary and reasonable" charge, or "UCR") for the service. The plan, using its own internal criteria and methodology, determined that the "usual and customary charge" for the cervical surgery was $29,890, and then paid the surgeon $23,912. Several weeks later, Jack was shocked when received a bill from his surgeon for $43,538. He expected that he would have to pay the standard copayment and the balance of his annual deductible but had no idea that his plan would pay so little or that his doctors would refuse to accept what the plan paid as payment in full, as they did the first time around. Jack had no complaint about the surgeon, but rather with his health plan; he assumed that if Dr. Jones wanted him to pay so much more the health plan must have paid far less than it should have. Jack called his plan administrator, wrote nasty and threatening letters, called his lawyer, and even called his representative in Congress. The plan administrator was relentless; the payment amount stood. Jack's lawyer explained that because the plan was employer funded Jack's remedies were limited by a federal law known as "ERISA,"[7] which vigorously protected the discretion of plan administrators to make claims payment decisions. Meanwhile, after three monthly statements the surgical group sent the bill to collection and Jack started getting dunning letters and phone calls. Jack also called the group and spoke several times with the office manager. Ms. Lowery explained that because the doctors no longer "participated" in his health plan Jack was responsible for any part of the bill that the insurance did not pay, and reminded him that when he registered for the surgery he had signed an "agreement" that he would pay any balances not covered by his insurance payments. She asked if he thought he might qualify as "medically indigent," which might allow some reduction in the balance due. His income and assets greatly exceeded the federal poverty threshold so he did not qualify. Jack persisted. If the doctors still were under contract with his health plan wouldn't the plan have paid even less, he asked? Wouldn't the doctors have had to accept that smaller payment if they were still under contract with the plan as in-network providers? Off the record, Ms. Lowery conceded that all of this was true and that, "in the old days," the surgeons might have accepted what the health plan paid as payment in full, but "now" they no longer could do so. She did not explain why.

For years insurance companies, health plans and other health care funding organizations established the "usual and customary" charges for thousands of medical and hospital procedure and service categories by relying on data put out by a company known as "Ingenix." Ingenix is the successor of several other companies and, in turn, is itself currently owned by United Health Group, one of the largest and best known health insurance companies in the nation. In principle the idea was sound: insurance companies, plans and other payers would report to a central repository all kinds of information about the medical claims they processed and the payments they made, to generate reliable data about what the "average,"

"fair," "reasonable," "actual" or "customary" charge for a service or treatment should be. These vague terms and nebulous concepts evolved in a financial and health care context very different from today. Before there was any "managed care," health plan benefit designs usually required the insurer or plan to indemnify a member patient for his or her health care expenses at some percentage or formula based on what was "usual and customary." Obviously, to do this there had to be some way of figuring out just what was "usual and customary." Under managed care more and more health care providers contracted with insurers and health plans to become "in-network" participating providers and accept payment at fixed rates negotiated and embodied in a contractual agreement. In most cases the rates either were a percentage of the providers' "actual charges" or, more often, a function of the type of service or treatment ("case-based" rates). With in-network providers paid on a case-based rate there is no need for a "usual and customary" rate schedule.

While managed care has dramatically changed over the years, two basic plan designs remained constant. The "health maintenance organization" concept, or HMO, requires strict "in network" discipline. True, in an emergency the member can use any provider. A health care "emergency" is very narrowly defined, however. In New York both Public Health Law section 4900(3) and Insurance Law section 3216(i)(9) define an "emergency condition" identically:

> An "emergency condition" means a medical or behavioral condition, the onset of which is sudden, that manifests itself by symptoms of sufficient severity, including severe pain, that a prudent layperson, possessing an average knowledge of medicine and health, could reasonably expect the absence of immediate medical attention to result in (A) placing the health of the person afflicted with such condition in serious jeopardy, or in the case of a behavioral condition placing the health of such person or others in serious jeopardy, or (B) serious impairment to such person's bodily functions; (C) serious dysfunction of any bodily organ or part of such person; or (D) serious disfigurement of such person.

In a non-emergency situation, however, (which may mean once the emergency patient is stable) the use of a provider not under contract to the network plan, that is, "out-of-network," is either completely excluded from coverage, meaning the plan pays nothing, or else is discouraged by penalties that require significant portions of a bill to be paid by the member directly out of his or her own pocket. (In most states even in emergencies the provider is not required to accept the payment as payment in full and may—and often does—pursue the member personally for all or a part of the balance not paid by the insurer. Only in California, because of a recent court case,[8] must the unhappy out-of-network emergency care provider fight it out with the insurer or plan and "hold harmless" the member-patient even though the provider is not under contract with the payer.) The "preferred provider organization" and some HMO plans with a "point of service" option, on the other hand, allow the member to use an "out-of-network" provider. Those plans often market themselves as a good choice for people who sometimes may want to use a non-network doctor, but require an additional premium payment which often is substantial. It is here that the "Ingenix" issue most often comes up, and here that the response of insurance companies and health plans pose such a dramatic dilemma to all participants in the health care delivery system.[9]

Summing up the long and convoluted history of the Ingenix controversy is not an easy task. About ten years ago several firms of class action attorneys were retained to bring suit against a number of major health insurers and plans that regularly relied on the Ingenix data. Some plaintiffs, like physicians and other health care providers, were unsatisfied with what they considered to be unreasonably low payments and did not want to pursue their own patients for the unpaid balances. Other plaintiffs were the member-patients themselves, who agreed that their insurers and plans had the right to pay based on what was "usual and customary" but argued that the methods used by payers to determine just how much was "UCR" had to be flawed to result in such paltry payments, which arguably denied the members the full benefits of their health insurance and also exposed them to collection activities and possible lawsuits based on the unpaid balances due to their providers. In the past few years there have been several major developments in these *Ingenix* litigations. In one consolidated class action,[10] a major insurer has agreed to pay $270 million to settle claims based in part on allegations of flawed Ingenix data. The actions challenged the way that HealthNet paid claims when members of HealthNet's health insurance plans use medical providers who were out-of-network. The plaintiffs alleged that HealthNet provided inadequate usual, customary and reasonable reimbursement to its members for covered services rendered by out-of-network providers because of its reliance on the Ingenix databases and/or other objectionable protocols or methods. The actions also challenged the quantity and quality of the information HealthNet provided about how it would pay for covered out-of-network services, how HealthNet explained its benefit denials and how it decided appeals from subscribers who disagreed with HealthNet's decisions. By an order dated September 25, 2006, the court certified the cases to proceed as class actions. On April 24, 2008, the court also preliminarily certified a settlement class.[11]

In a second case, *American Medical Association, et al. v. United Healthcare Corp, et al*.[12] in which the class plaintiffs raised similar allegations against United Healthcare, a proposed settlement offer of $350 million initially was rejected by the court as possibly inadequate. On December 1, 2009, however, after a further hearing, the court issued preliminary approval.[13]

In approving the *HealthNet* class action settlement the federal district court judge, the Hon. Faith S. Hochberg, summed up her findings respecting the problems with the *Ingenix* methodologies. First, the judge identified two serious flaws in Ingenix's data collection methods. The database is compiled from data submitted by several insurers under a purely voluntary "data contribution program." Only those health insurers that are Ingenix clients get to submit information (yes, the parties that draw the UCR data *out* of the system are the ones controlling the data that first goes *in*) but on a purely voluntary basis. Contributing plans provide data about the amounts they have been billed by an *undisclosed* number of *unidentified* health care providers for specific service and procedure "codes" (the standard shorthand used in health care to report and bill specific treatments and procedures). The Ingenix database includes the bills of an unspecified number of medical providers who happened to have billed only those health insurers that were not only Ingenix clients, but also Ingenix clients that participated in Ingenix's voluntary data contribution program. The judge explained that this type of "convenience" sampling is the easiest way to collect data, but it is haphazard. "Convenience" samples are chosen on the basis of expediency, cost, efficiency or other reasons not directly concerned with scientific sampling parameters that promote accuracy. As a result, convenience samples are considered the most suspect type of sample.

Second, Ingenix did not test the voluntarily submitted data to see if the data really was an accurate representative sample of charges for particular procedures in particular geographical areas. Also, the data collection methods provided no assurance that the raw data collected represented the actual charges billed for any given procedure. This was because the companies that submitted data received a discount based on the amount of usable data they sent in. This encouraged insurers to "remove" high charges before submitting their data, so that such data would not later be deleted by Ingenix during the subsequent "data scrubbing" process which routinely is conducted to assure that "outliers" and other rare or unusual high cost procedures do not skew the results. (Oddly, neither the plans in their initial data submissions nor Ingenix in its later "data scrubbing" routinely removed *low charge* outliers.) Since other insurance companies that also use the database are permitted to choose what data to send in there is a built in incentive to submit low cost data that will produce a lower UCR database, which the submitting insurance company itself later will use to calculate a lower UCR for its own payments for out-of-network services for its insured members.

Next, the judge found that the database relied upon too few data "points" for each procedure. The database relies upon just four "points," or pieces of data, for each submitted charge: the date of the service; the standard codes I referred to above; the address where the procedure was performed; and the amount of the provider's billed charge. However, it excluded several factors that are critical to the core concepts of UCR. These four data points do not identify (1) the provider's licensure or qualifications; (2) the patient's age or health status; or (3) the type of facility where the procedure was performed. The database does not take into account whether a particular procedure was performed by a highly skilled Board-certified specialist or a general practitioner or a paraprofessional or a nurse. One would expect that it would cost more to have a highly skilled, Board-certified heart specialist read your echocardiogram than it would to have a family physician do it. Likewise, a procedure performed by a highly skilled physician is more expensive than one performed by a physician's assistant or nurse practitioner. The physician's higher charge is the most valid point if the bill being processed by the insurance company is for a patient who was treated by a physician of comparable skill and experience. Yet by including every possible type of provider in the standard codes submitted, even a totally average bill from a skilled physician will be higher than the UCR yielded by the database. These excluded data points may be the most important factor in determining "reasonable" and "customary" costs. The database improperly assumes that these factors are all irrelevant for determining the usual and customary rate charged for particular procedures. Any accurate database would control for these additional factors. Ingenix's failure to control for these factors, the court found, means that the database is not actually comparing similarly situated procedures when it claims that it results in the "usual" and "customary" rate for that procedure and pays a bill on that basis.

There were a number of other statistically significant issues which the court found to support a conclusion that the database, as a whole, was seriously flawed.

Another major *Ingenix* development is the historic settlements entered into between the Attorney General of New York, Andrew Cuomo, and fifteen major health insurers and plans, under which each of them has agreed not only to abandon the use of the Ingenix database but also to contribute in excess of $100 million for the development of a replacement. Evidently building upon developments in the litigation arena the New York Attorney General opened a number of inquiries addressed to the several large health plans and insurers operating in New York. Over the past year or so regular press releases would advise that settlements were being reached with

each of these plans. The most recent release, on October 27, 2009, which announced the formation of the new consortium, reiterated the terms of the previous settlements. (There were no admissions of wrongdoing or any tacit or express acknowledgements of liability in any of the settlements.):

> Ingenix, a subsidiary of UnitedHealth, was used by insurers nationwide to set reimbursement rates when patients went out-of-network for health services. The Attorney General's investigation found that as a subsidiary of the second-largest insurer in the nation, Ingenix had a vested interest in helping set rates low, so companies could underpay patients for out-of-network services.
>
> The investigation revealed that the database intentionally skewed "usual and customary" rates downward through faulty data collection, poor pooling procedures, and the lack of audits, meaning consumers were forced to pay more than they should have. The rate of underpayment by insurers ranged from ten to twenty-eight percent for various medical services across the state. The Attorney General found that having a health insurer determine the "usual and customary" rate—a large portion of which the insurer then reimburses—creates an incentive for the insurer to manipulate the rate downward.
>
> Approximately 70 percent of insured working families have out-of-network plans that let them choose their own doctors and the system impacts one in three individuals, or over 110 million people nationwide.[14]

In light of the regulatory and litigation situations, sooner or later the Ingenix databases will be a thing of the past. While the actual financial impact on insurers and health plans cannot be determined now, what is clear is that UCR payments will go up—*way up*—and payers of all kinds will have to pay hundreds of millions of dollars more each year in higher UCR claims. At the same time consumers of health care continue to demand choices in their doctors and other health care providers, forcing insurers and plans to keep offering "point of service" and "out-of-network" benefit designs to remain competitive. Meanwhile, more and more hospital systems and medical providers, especially Board certified specialists, are refusing to accept the low rates that go hand in hand with "in-network" participation contracting and are going "out-of-network" because of the higher reimbursement—actual or potential—that such an option affords. These developments placed health insurers and plans in a quandary. When most health insurance was simply another kind of indemnity insurance plan, insurers and payers cared little if at all whether the doctor collected the difference between what was billed and what the plan paid. If the provider and the patient made a deal, that was strictly between them. No one made the insurance company pay more than it decided to pay and no one told it how to figure that out. Later, when managed care came along and some plans had out-of-network benefits, we still never saw any plan insisting that the provider demand payment in full. Plans determined their share based on the industry-generated formulas for UCR and walked away. Now that insurers and other payers are faced with government interference in their out-of-network payment schemes and the prospect of a fair and objective method of determining UCR, with the large payment increases that are expected to accompany such reform, something dramatic had to be done. It was only a matter of time before health care providers saw the opening salvos of the counterattack.

Recently a major health plan in New Jersey sued a former in-network provider for fraud and interference with contractual relations because the provider decided not to go after its out-of-network members for any patient balances. The case is *Horizon Blue Cross Blue Shield of New Jersey v. East Brunswick Surgery Center, et al.*[15]

East Brunswick Surgery Center (EBSC) terminated its network contract with Horizon of New Jersey, ostensibly because the parties could not come to a renewed agreement on negotiated rates of payment. According to Horizon's allegations in the state court complaint East Brunswick then "dramatically increase[d] its charges for services rendered to Plaintiff's subscribers" who were out-of-network, and it routinely waived copayments and deductibles, allegedly "in order to induce [Horizon's] subscribers to use its services." There is no allegation that East Brunswick targeted Horizon specifically, however.

Horizon first went into state court and sued EBSC for fraudulently interfering with Horizon's in-network benefit plans. Horizon alleged insurance fraud, common law fraud, negligent misrepresentation and tortious interference with its existing contracts with its members, claiming that EBSC cost it over $5,700,000 in excess or overbilled charges. In an unusual twist EBSC, the *provider,* removed the case to federal court, arguing ERISA preemption, but the federal court remanded it.[16]

For providers, the ERISA issue is really just a sideshow. The issue with the most impact is whether and to what extent a non-participating provider may bill a plan for full charges while explicitly or implicitly agreeing *in advance* of rendering services that it will waive any patient responsible shares.

The main arguments in the Horizon complaint are these. First, EBSC knew that Horizon's out-of-network benefit designs required members to pay copayments and coinsurance and to meet deductibles. In fact, Horizon alleges, each time EBSC called to verify coverage and eligibility it was told what those obligations were (although there is no allegation that a Horizon representative ever directly stated to the caller that the payments could not be waived). Horizon claims that by agreeing to waive copayments and deductibles in advance of a procedure, EBSC was deliberately *overstating* the billing for its services when it submitted its out-of-network claims for payment because it should have been submitting its actual charges *less* what it knew it was supposed to get paid directly by the member. Horizon argues that EBSC knew that Horizon based its payments on the amount of charges actually billed and that Horizon would pay based on the submitted charges; therefore the billings were fraudulent and intended to mislead Horizon.

Secondly, a Horizon member who uses out-of-network benefits is required by his or her member agreement (i.e., the insurance contract to which he or she subscribes—knowingly or unknowingly—when joining the group plan) to absorb deductibles and make copayments. This "disincentive" to the use of an out-of-network provider is intentional but perfectly proper, because it advances the entire idea of "managed care" and of limiting unnecessary and overly costly utilization. When EBSC waives the member responsible shares, the argument goes, it is inducing the member to breach his or her own member agreement with Horizon requiring that he or she will pay the patient shares.

Lastly, Horizon alleges that the billing practices of EBSC violate state insurance fraud laws.

EBSC's attorneys filed an answer in the remanded state court proceeding, in which they generally deny the substantive allegations of the complaint. They also raise affirmative defenses based on statutes of limitations, waiver, estoppel, the absence of indispensible parties and the failure of Horizon to state a legal claim upon which relief may be based.

It is possible that Horizon pays out-of-network claims based on the actual charges billed by the providers. Some plans do; usually those acting solely as administrators on behalf of self funded ERISA customers for whom they receive and process claims and other paperwork and pay out the fund's money in exchange for fees. The administrators do not incur any financial risk themselves. (Many traditional health insurers also operate this kind of business, giving self-funded plans and payers the same access to their in-network provider agreements as is given to those who buy into risk products by paying premiums.) When a plan pays based on its own arbitrary, unilateral determination about what the UCR should be for a given service, however, often by relying upon the Ingenix data, it does not matter what amount the provider billed as its "actual charges." Even in cases where plans may pay based on a percentage of billed charges, the particular benefit design almost always imposes some kind of limitation on the actual charges the payer will entertain regardless of what the provider actually bills. The effect of such a cap, ceiling, outlier or "stop loss" arbitrarily established by the payer means that it is not truly entertaining provider claims at the "actual charges" billed.

In any event, how is the provider even to know in advance of billing what the member's out-of-network responsible share to be? That amount usually is not known until a claim is processed and an explanation of benefits is issued by the payer.[17]

If, as Horizon alleges, EBSC notifies Horizon members in advance that their copayments and deductibles will be waived and the member elects to have the procedure anyway, is the member in breach of his or her member agreement with Horizon? Would Horizon have a cause of action against its own member? Keep in mind the reality that most members are not individual enrollees but are parts of group plans where the members never even see the member contract; they agree to be bound by the terms when they join the group (usually when they first become employed). If the members are not actually aware of the requirement can their failure to comply be held to be a breach? If so, is the breach material? If it is not material as to the members' conduct, can it be material as to the provider?

Another important issue is whether EBSC induced the Horizon members to breach because of some *unlawful or improper conduct* on the part of EBSC. Horizon does not allege that it was the target of any improper activity by EBSC, or that EBSC solicited Horizon's members exclusively. As best as I can determine, the EBSC policy of waiving copayments and deductibles applied to any member of any health plan that had out-of-network benefits, not just Horizon's.

The elements of tortious interference with a contract (or with contractual relations) recognized in most jurisdictions are:

1. The existence of a contractual relationship or beneficial business relationship between two parties.
2. Knowledge of that relationship by a third party.
3. Intent of the third party to induce a party to the relationship to breach the relationship.
4. Lack of any privilege on the part of the third party to induce such a breach.
5. Damage to the party against whom the breach occurs.

What may be particularly relevant in this case is item "4"—the question of whether the defendant is somehow privileged or entitled to act as it did. In other words, given that the conduct actually took place, was the result—the alleged breach by some third party of its contract with the plaintiff—excused or justified? In New York and some other jurisdictions, in certain circumstances a valid business or economic reason for an action or omission may constitute a defense to a claim of tortious interference, even if those acts actually induce a breach of a contract, when the business interest causing the defendant to act is "equal to or greater than" the business interest of the plaintiff.[18] Obviously this implies a qualitative inquiry. When the adverse parties are competitors, for example, the defendant's general business interest in "growing its business" is not enough to save it.[19] Much of the case law turns on situations in which a defendant either is a competitor of the plaintiff or has some ownership interest in the plaintiff company and arguably is acting to protect its interest in the face of the plaintiff's opposition. Here, however, where the parties are *not* competitors, different criteria must be applied in establishing whether the legitimate interests of EBSC excuse any incidental contract breaches by Horizon members. For example, the New York Court of Appeals recently held that sending regular advertising and soliciting business in the normal course does not constitute inducement of breach of contract. Liability will depend on a showing that the inducement exceeded a minimum level of ethical behavior in the marketplace.[20] Ultimately a court may have to determine whether the business interests and economic realities faced by medical providers operating in out-of-network environments which justify decisions to "lower prices" will outweigh the legitimate business interests of insurers and other payers in enforcing contractual restrictions on their members that "encourage" in network utilization.

Courts also may consider whether the provision of the member contract which Horizon says is being breached, i.e., the obligation of a member using an out-of-network provider to pay deductibles and copayments, is something Horizon could enforce even if it wanted. Health plans implicitly acknowledge that one of the purposes of the requirement is to make out-of-network care more costly to the member, hence incentivizing him or her to remain in network. This is incongruous, however, given that most benefit designs allowing out-of-network access charge a *higher* premium for that privilege. How would a court react to the argument that the law should permit a plan to discourage a member who pays more for the right to access out-of-network providers from using the very benefit for which he or she paid extra? Horizon's self-serving position on this point is problematic, especially when some plans and plan administrators are held to a higher standard of fairness (sometimes, in an ERISA context, even to the level of a fiduciary[21]) when the plan benefits financially from procedures and decisions that go against its own members' financial interests. I have never seen a member agreement that states that a member *must* pay the patient share. Yes, network provider agreements often prohibit participating network providers from waiving copayments and deductibles, and member agreements hold that the payment of such balances is the member's personal responsibility. That is not quite the same, however, as a provision expressly stating that the member must pay, or that the member may not accept a provider accommodation. Even if the court were to find such an obligation in the agreement in question, will the court enforce it against the *provider*? Such a holding well may be the functional equivalent of *prohibiting* a member from accepting medical care from the provider if he or she knows that the patient shares will be waived. On the other hand, if the contract provision allegedly breached by the member is not enforceable in court then the actions of a defendant allegedly inducing the member to breach that provision arguably are not actionable as a tortious interference.

Lastly, and perhaps most importantly, if Horizon knew in advance of the payment of a claim that EBSC agreed to waive patient shares, then arguably it did not rely on any material misrepresentation in the amount of the billing. If Horizon nevertheless entertained and paid the claim can it later be heard to argue that it was defrauded?

On the issue of fraud, Horizon also alleges that EBSC violated New Jersey's Insurance Fraud Prevention Act, N.J.S.A. 17:33A-1, *et seq*. However, nothing in that statute says that EBSC cannot waive copayments and deductibles. The statute, rather, is a broadly stated proscription on activities that perpetrate fraudulent insurance claims:

> A person or a practitioner violates this act if he: (1) presents or causes to be presented…a claim for payment…*knowing* that the statement contains any false or misleading information concerning any fact or thing material to the claim;…

NJSA 17:33A-4. (*emphasis added*)

This being the case, a resolution of this issue appears to turn not on whether EBSC waived copayments but on whether EBSC's use of actual charges in its billing constituted a "knowing" use of "false or misleading information." This point is driven home by a late-breaking decision out of the New Jersey Superior Court Appellate Division which, in its holdings in a similar case, found that even though the out-of-network provider never collected a copayment, it nevertheless did not "know" at the time it billed whether it would demand that the member honor his or her obligation to pay such balances.[22] Whether and to what extent Horizon will be deemed to have waived any objection to EBSC's conduct by its knowing acceptance and payment of claims which it now alleges to be fraudulent, or whether it is estopped from

raising the objection at this time, is something a trial may have to determine.[23]

As more providers find that they cannot live with inadequate network reimbursement rates these issues will take on greater importance. This is especially so given the recent initiatives by the New York Health and Insurance Departments to address out-of-network claims by specialists and the impact that balance billing has on the patients.[24] The bigger problem for the community of health care providers is that the Horizon suit is just the tip of the iceberg. Horizon has similar lawsuits pending against other out-of-network providers, and all the evidence points to this as a growing trend. Health plans and insurers have to keep offering members different "point of service" and out-of-network benefit designs, but are frightened of the consequences of abandoning the Ingenix database and having to pay claims at more objective—and much more expensive—newly established UCRs. Suing members to force them to pay their providers' balances is bad for business. The obvious answer is to discourage the use of out-of-network benefits, even when members pay more for the privilege, by forcing the providers to collect from those members every penny that they actually bill, regardless of how much the member has to pay out of pocket. If the plans succeed in driving away enough out-of-network patient business hospitals and doctors will be forced again to become in-network participating providers, agreeing to accept the much lower rates negotiated during the contracting process and making the entire Ingenix out-of-network mess go away.

This may explain why the office manager suggested to Jack that in the past the surgeon would have accepted whatever the plan paid, but now he cannot. The truth is that he may be afraid of what the plan will do, and with good reason. A few weeks after receiving the explanation of benefits from his plan administrator, telling him what it paid the surgeon, Jack received an interesting letter from his health plan. It looked almost like a quality survey, with a few questions about Jack's experiences and whether he was satisfied with his care. Then it became strange. It asked questions about whether Jack was told by the surgeon, in advance, how much he would have to pay over and above what the plan paid. It asked whether Jack and the surgeon had made a "deal" on the amount of Jack's balance. It asked whether the surgeon had actually billed Jack, whether Jack was making payments, and whether Jack was destitute, on public assistance, or in need of some "consideration" due to his financial circumstances. All of this made Jack very uncomfortable. Wasn't all of this rather private, a matter between him and his doctor? At the suggestion of his lawyer Jack did not respond. Jack was concerned that he would have trouble with his health plan but the lawyer assured Jack that nothing in his member agreement or the law would allow the plan to take back the claim payment if Jack did not respond.

The lawyer also had something to say about the surgeon's "balance billing" to Jack. Yes; it was legal for Dr. Jones to "balance bill" for the difference. There was no law or contract requiring Dr. Jones to accept anything less than the "actual charges," the full retail charges, for which he initially billed the plan. But in health care, as in commercial activities generally, there is another important element that impacts on the issue—the "fair and reasonable value" of the provider's services.

The last refuge of provider reimbursement has always been the billing of services at "full charges," "actual charges," "listed charges" or by whatever a provider prefers to call the data in its retail charge database (for hospitals it is called the "charge description master"). If reimbursement is not dictated by government regulation[25] or by the express terms of a contractual agreement with a payer network, the provider may bill full charges. If pricing is not regulated, and if the market continues to treat health care as it does any other commodity, a provider legally may develop its charges by whatever methods it chooses and may demand that the recipients of its services pay accordingly. However, what the provider demands is not what it necessarily must be paid. In the absence of an express agreement in advance, a provider's demand for full payment of charges may be met by the defense that the demand must be limited to the "fair and reasonable value" of such care and services or, in the language of the law, limited to "quantum meruit."[26] Whether fixed contract terms exist (either by an express agreement or as implied from the facts) or whether the law will create the fiction of a contract where there is none (and thus apply "quantum meruit" as the payment term) depends upon the legal nature of the relationship between the patient, the payer and the provider. Further complicating the environment is the recognition that although contract law evolved in a commercial context, health care transcends the "marketplace" and is often treated by courts as much a basic human right as a commodity, thus affecting any legal analysis of the relationships between health care suppliers and health care consumers.

Providers appreciate that the likelihood of recovering the entire unpaid balance, especially a large one, directly from the patient is remote because most patients do not have the financial resources to answer for large medical debts, so providers may elect to pursue the nonparticipating payer if the provider has taken a valid assignment of benefits and otherwise has standing to do so.[27] Sometimes the patient is uninsured but has the resources to pay the debt in full, so the provider seeks payment of full charges from the patient. Any of these situations may result in the provider instituting litigation, where the principle of "quantum meruit" may be relevant. If there is no express or implied contracted rate courts almost always limit the payment due for health services to the "reasonable value" of such services, and a claim based on "full charges," without a concomitant showing of "reasonableness," is

never held to serve as the basis for a recovery. This means that, in the vast majority of cases, if a provider has to litigate to recover a balance due, it will not recover solely on the basis of its charge description master. Instead the provider, as the plaintiff, will bear the burden of proving that the sums it demands are the "reasonable value" of its services regardless of what its charges may be. A provider may have to meet this burden every time it sues, depending upon the determination of the defendant.[28] While most courts agree on the "reasonable value" standard, the cases do not offer any real guidance as to how the determination is made because a resolution is so fact specific. Even the federal government, in reviewing Medicare regulations many years ago, declined to adopt a standard definition, recognizing instead that there were so many different factors that a definition was not practical. This has left courts to apply a variety of common law principles and factual analyses on a case by case basis.[29]

In New York the law is that a hospital's charges to an uninsured patient—indigent or otherwise—are not unreasonable *merely* because a lower price is charged to government programs or to insurers.[30] It is well settled that in exchange for network participation (implying steerage and volume) and prompt payment, a provider of health care services is legally and commercially justified in offering discounted rates to insurers and other third party payers. However, a Pennsylvania court recently held that a hospital's full charges were unreasonable because almost no one ever paid full charges, even though the dollar amount of the charges themselves were comparable to what every other area hospital charged.[31] Several significant decisions in different states also turn on the same argument—that routine, across the board "discounts" of charges in a number of contexts were strong evidence that the stated charges were *prima facie* unreasonable.

In the meantime a recent New Jersey decision went so far as to hold that an uninsured patient's written agreement to pay "charges" was unenforceable because there was no realistic "bargaining" between the parties; the document did not disclose the applicable rates for the contemplated services and the patient was not in a position to bargain meaningfully because his condition required immediate treatment. The idea behind a finding that a proffered agreement is an unenforceable "contract of adhesion" is that the patient could not refuse the medical care regardless of the "price" and he could not "shop around" for a better deal because his need was urgent. In addition, the New Jersey court looked to the Medicare reimbursement rate as one measure of the "reasonable" value of services because the Medicare rate was accepted by that particular hospital, thus following a growing trend in courts across the country to use Medicare rates as a benchmark.[32] Differing on the effect of a payment guarantee given at admission, a Missouri appellate court upheld the validity of a self pay patient's agreement requiring payment of "charges," but only because it found that the charges were "reasonable." It also expressly held that the agreement was enforceable because the patient expected to pay "reasonable" charges and that was what he was being asked to do.[33]

Further compromising the traditional defense of commercial justification for discounted rates is the increase in the application of "high deductible" and "limited benefit" health plan designs. When larger and larger portions of discounted rates become payable by the member directly rather than by the plan it is harder to escape the argument that the discount is not a *bona fide* consideration for steerage and prompt payment. It will not be long before some clever attorney successfully argues that since so great a part of the discounted rate is paid directly by the member anyway, there is no valid justification for the distinction when a provider balance bills the patient.[34]

What is being done about this mess? On October 7, 2008, the New York State Departments of Insurance and Health conducted a public hearing on the issue of billing out-of-network patients. While the emphasis appeared primarily to be on physician balance billing there is no reason to believe that any regulations eventually promulgated will not affect hospitals as well. Relevant portions of the press release announcing the hearing are as follows:

> "Consumers are put in an impossible position," [Insurance Superintendent] Dinallo said. "They follow the rules of their health insurers and receive care from a participating doctor and hospital, believing that all related services—such as laboratory, anesthesiology and pathology—will be covered at the in-network rate. Despite their best efforts to stay in-network, consumers are often shocked to get a big bill because the anesthesiologist or pathologist is not in their health plan's network."
>
> The Insurance Department has received numerous complaints from consumers who received care from a participating doctor or hospital, yet related specialty services were either denied or covered as out-of-network. Often, the consumer had no choice in selecting the specialist or may not have been told the specialist was non-participating.
>
> These types of issues are not limited to cases when a consumer is able to schedule health care services in advance. In fact, these issues are even more prevalent in emergency situations since a consumer is often unable to choose where to receive services. And even if a hospital

participates in a health plan's network, there is no guarantee that the emergency room physician or the anesthesiologist will also participate with the health plan. In such cases, consumers may be faced with exorbitant bills for the emergency services for which their health plan will only pay a portion.

The Insurance Department and Department of Health are considering statutory and regulatory changes to address these issues and would like to receive input from consumers, health plans, providers and other interested parties.[35]

While plan and insurance representatives uniformly applauded initiatives to preclude any "balance billing," provider representatives and in particular physicians effectively argue that taking the patient out of the paradigm leaves the providers at the mercy of the plans with little recourse, especially when disputes are over relatively small dollar amounts. Patients no longer have a reason to advocate for additional payment or even cooperate with provider appeals. Several specialists who generally are not in-network with any plan (such as plastic surgeons) frankly stated that they would close their practices and leave the state if compelled to accept payments that do not even cover their malpractice premiums.

Will the "new" database being developed by the Attorney General's consortium solve the problem? It will be a dramatic improvement if data collection is mandatory for all health payers and if providers and payers both are bound by the results. That second "if" is the big one. It is legally questionable whether anyone may be compelled against his or her consent to accept a fixed rate of payment for professional services, such as by the imposition of mandatory fee schedules for non-emergency as well as urgent care services. In any event it will take years for the new database to be developed, rolled out and accepted across the board by providers and payers.

On his lawyer's advice Jack declined to pay the surgeon anything more than what already had been paid by his health plan. He was scheduled for a follow-up appointment a week later and needed to tell Dr. Jones about a stabbing pain that he was having in his neck, but the balance billing situation made Jack so uncomfortable and embarrassed that he made up some excuse to cancel his appointment. He did not reschedule.

Where does this leave us? With a broken health care payment system that forces doctors to work harder yet spend less time with each patient; to exchange a greater certainty of payment for unreasonably low payments; to jeopardize the intimacy and trust that is absolutely essential to the physician-patient relationship because of health plan interference in their financial arrangements. With a system that makes patients pay more for the illusion of additional health care coverage when no patient would ever want to use that benefit; that exposes patients to large personal balances when they thought they had adequate coverage for their medical and hospital care; and that drives patients away from necessary follow-up care and long term relationships with their doctors because the doctors no longer can work with the patients to accommodate financial issues.

Endnotes

1. A "preferred provider organization," not established or defined by law but universally understood to be a network of providers agreeing to accept a schedule of contracted rates for covered services if a variety of eligibility and administrative requirements are met. Traditionally, self funded Taft-Hartley plans governed by ERISA will participate in PPO networks that administer plan funds, rather than buy into risk products (i.e., pay premiums for the fully insured products) offered by HMOs.
2. A "health maintenance organization" established by federal and state law and defined by New York Public Health Law Article 44 (Secs. 4401 *et seq*.).
3. The authority of a hospital effectively to act as an agent of the private attending physicians by securing record authorizations, treatment consents and payment guarantees has yet to be discussed, and in an appropriate case may be dispositive on the issue of the validity of any such obligation.
4. Providers not under contract in a network, thus not in privity with a plan or payer, must rely upon an assignment of benefits to seek payment of claims directly from the plan and effect legal redress if necessary. Providers under contract usually but not always resort to direct contractual remedies against a plan. In an ERISA context, however, whether and to what extent a provider is advantaged or prejudiced by its reliance upon the "beneficiary's" assignment of benefits has been the subject of significant litigation. Providers that assert claims based on a beneficiary's assignment of benefits may find themselves limited only to the precise remedies established under ERISA were the beneficiary suing directly, rather than state and common law remedies otherwise available if the provider were suing directly as a party to a network agreement with a plan. Providers must proceed cautiously. *See, e.g.*, *Montefiore Medical Center v. Teamsters Local 272*, 2009. U.S. Dist. LEXIS 105832 (09 Civ. 3096).
5. An assignment of benefits will require a plan or payer to tender payment directly to the provider as assignee even if the provider is out-of-network. Many ERISA plans, however, and a growing number of commercial plans as well are incorporating "anti-assignment" clauses into their member agreements. These clauses effectively deny the member the authority to assign any benefit of payment or of any cause of action to the provider. *See, e.g., Cole v. Metropolitan Life Insurance Co.*, 273 A.D.2d 832, 708 N.Y.S.2d 789 (2000); *see also, American Medical Association v. United Healthcare*, 2001 U.S. Dist. LEXIS 10818; 26 Employee Benefits Cas. (BNA) 1897.

   The astute reader will appreciate the not so subtle effect of such a practice on "encouraging" recalcitrant providers to sign up as "in network" and avoid the myriad of collection headaches that invariably result when a plan sends a six figure check to its own member.
6. "Actual charges" in the context of health care is as vague a concept as is "retail charges" in any commodity marketing context. In theory, "actual charges" should reflect all of the supplier's costs together with whatever margin of profit the market will bear as a function of competition and demand. In the tightly regulated health care marketplace, however, it is anyone's guess. In the

thirty years or so since market pricing began moving away from indemnity models third party payments were calculated not so much on retail charges as on a variety of regulated methodologies and mandated fee schedules. (In New York, see the history of Public Health Law section 2805, in particular subsection c, as it moved from indemnity to the Prospective Healthcare Reimbursement System ["NYPHRM"] to the Health Care Reform Act ["HCRA"]). Actual billed charges were basically irrelevant. With the explosion of uninsured and underinsured patients and the resulting billings to the patients themselves, which obviously are based on "actual charges," this issue is becoming more problematic. See *infra.*

7. *Aetna Health Inc. v. Davila*:

> Congress enacted ERISA to "protect…the interests of participants in employee benefit plans and their beneficiaries" by setting out substantive regulatory requirements for employee benefit plans and to "provid[e] for appropriate remedies, sanctions, and ready access to the Federal courts." The purpose of ERISA is to provide a uniform regulatory regime over employee benefit plans. To this end, ERISA includes expansive pre-emption provisions, see ERISA § 514 which are intended to ensure that employee benefit plan regulation would be "exclusively a federal concern."
>
> ERISA's "comprehensive legislative scheme" includes "an integrated system of procedures for enforcement." This integrated enforcement mechanism, ERISA § 502(a), is a distinctive feature of ERISA, and essential to accomplish Congress' purpose of creating a comprehensive statute for the regulation of employee benefit plans.
>
> Therefore, any state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted.
>
> …
>
> This provision is relatively straightforward. If a participant or beneficiary believes that benefits promised to him under the terms of the plan are not provided, he can bring suit seeking provision of those benefits. A participant or beneficiary can also bring suit generically to "enforce his rights" under the plan, or to clarify any of his rights to future benefits. Any dispute over the precise terms of the plan is resolved by a court under a *de novo* review standard, unless the terms of the plan "giv[e] the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan."
>
> It follows that if an individual brings suit complaining of a denial of coverage for medical care, where the individual is entitled to such coverage only because of the terms of an ERISA-regulated employee benefit plan, and where no legal duty (state or federal) independent of ERISA or the plan terms is violated, then the suit falls "within the scope of" ERISA § 502(a)(1)(B). In other words, if an individual, at some point in time, could have brought his claim under **ERISA § 502(a)(1)(B)**, and where there is no other independent legal duty that is implicated by a defendant's actions, then the individual's cause of action is completely pre-empted by **ERISA § 502(a)(1)(B)**.

542 U.S. 209-210; most citations omitted; emphasis mine.

8. *Prospect Medical Group v. Northridge Emergency Medical Group*, 45 Cal. 4th 497; 198 P. 3d 86; 87 Cal. Rptr 3d 299; 2009 Cal. LEXIS 25; Jan 8, 2009).
9. More recently HMOs have morphed by including some limited "point of service" options to broaden provider networks and make their products competitive with PPOs on this issue.
10. *McCoy v. HealthNet, et al*., 03-CV-1801.
11. See the *HealthNet Class Action Information* website at: http://www.healthnetclassaction.com/Page.aspx?siteTextId=1).
12. 00-CV-2800 (SDNY 2000).
13. See, 2009 U.S. Dist. LEXIS 45610 (May 7, 2009); 2009 U.S. LEXIS Dist. 112634 (Dec. 1, 2009).
14. http://www.oag.state.ny.us/media_center/2009/oct/oct27a_09.html.
15. Filed in the New Jersey Superior Court, Camden Chancery, under docket no. CAM-C-97-08.
16. The federal court held that Horizon's allegations involve business relationships having nothing to do with reimbursement of member claims based on ERISA-controlled health benefit plans. Instead they involve a dispute between companies in furtherance of their own business interests, and in particular one company trying to protect its contractual agreements. The court found that the state claims were not preempted by ERISA and sent the case back to the New Jersey state courts. 2009 U.S. Dist. LEXIS 34397.
17. This is generally true regardless of what pre-service verification protocol is employed by a given provider. The patient share flows from the plan payment. The plan cannot calculate UCR until it actually receives a claim from the provider, and the provider cannot generate an accurate bill until after service is rendered.
18. It is questionable whether the concept of tortious interference should even be applied absent a competitive relationship between the parties. See, for example, the discussion in *White Plains Coat & Apron Co, Inc. v. Cintas Corp. et al*., 8 N.Y.3d 422; 867 N.E.2d 381; 835 N.Y.S.2d 530; 2007 N.Y. LEXIS 847.
19. "When the defendant is simply a competitor of the plaintiff seeking prospective customers and plaintiff has a customer under contract for a definite period, defendant's interest is not equal to that of plaintiff and would not justify defendant's inducing the customer to breach the existing contract." 2 NY PJI 2d 3:56, at 507-508.
20. Competitive conduct permitted under antitrust laws should never be punishable as tortious interference, as such conduct by definition cannot be inspired by "improper motive" or effected by "improper means": "[S]uch common law 'back dooring' would subvert the function of antitrust law in defining, and regulating, the boundary between permissible and impermissible competitive conduct." *Willamette Dental Group PC v. Oregon Dental Service Corp.*, 130 Ore. App. 487. 882 P.2d 637; 1994 Ore. App. LEXIS 1445.
21. *Firestone Tire and Rubber Co. v. Bruch*, 489 U.S. 101, 109 S. Ct. 948, 103 L. Ed. 2d 80 (1989). A denial of benefits challenged under ERISA "is to be reviewed under a *de novo* standard, unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." *Id.* at 115. If the plan does explicitly confer discretionary authority on an administrator courts must review benefit determinations under an "arbitrary and capricious" standard.
22. *Garcia v. HealthNet of New Jersey* (docket A-2430-07T3; Sup. Ct. App. Div., 11-17-09; http://www.judiciary.state.nj.us/opinions/a2430-07.pdf.
23. In an unreported decision in 2003, a Nassau County, New York judge decided an action in which Long Island Pulmonary Associates ("LIPA") sued Metropolitan Life Insurance Company ("MetLife") for payment for denied claims. (Sup. Ct., Nassau Co. NYLJ 2-14-03). MetLife counterclaimed for damages on theories of

unjust enrichment, fraud and tortious interference. It alleged that LIPA, which was out-of-network, accepted the 80 percent of UCR that MetLife paid when LIPA knew that it would not balance bill the members even though it billed MetLife for full charges. The court found that:

> …plainly [LIPA] made a false statement about the amount of fees charged the patient when it represented in a statement submitted to [MetLife] that the fee for services was 20 percent more than the fee to be accepted. It is also plain that [LIPA] intended [MetLife] to rely upon the statement.…The damage to [MetLife] is that it paid 20% more than it should have in paying 80% of a false fee, and the system designed to control health care costs was undermined.

. As to the all important issue of tortious interference the court held as follows:

> The only element requiring serious consideration is whether [LIPA]'s conduct induced Empire Plan enrollees to breach their agreement with their insurer. The answer is in the affirmative; they would naturally be drawn to and accept treatment from a healthcare provider who demanded no fee from them. Such patients, treated without any cost… would not even go to a participating doctor and pay the co-payment required by the Empire Plan.… No justification is apparent.

24. Joint Public Hearings on "Surprise Out-of-network Medical Bills" October 7, 2008 http://www.ins.state.ny.us/health/outnetagenda.pdf.

25. The "regular" Medicare and Medicaid programs and state regulated workers' compensation and "no fault" insurance all establish "fee for service" schedules and providers choosing to service enrollees in these programs are required to accept the fee for service rates as payment in full (less established copayments and deductibles). Medicare "Advantage" HMOs and Medicaid HMOs (and the very few workers' compensation and "no fault" HMOs that have appeared around the country) are akin to commercial managed care products in that they develop their own contracted networks and negotiate rates directly with participating providers. Most Medicare and Medicaid HMO products do not have any out-of-network benefits for non-emergency services.

26. Quantum Meruit: "as much as one deserves." A measure of recovery based on the actual value of services performed, derived from an "implied at law" contract , which is a fiction of equity jurisprudence, created when there is no true contract (no "meeting of the minds") and thus no agreement as to the amount of compensation required for the service, yet where it would be unfair for the recipient to retain the value of the services when there was a reasonable expectation that payment would be made. To avoid unfairness the law implies that a contract exists, and then goes on to determine the "fair and reasonable" value of the services from a variety of circumstances which are unique to the facts at hand but which follow generally accepted legal (read "equitable") principles in the interpretation of those facts.

27. The assignee "stands in the shoes" of the assignor and takes no greater or fewer rights than the assignor holds in the first instance. The law of assignment generally permits the assignment of the benefits of an agreement without delegating the duties or obligations, but this does not mean that those duties and obligations disappear. Someone must satisfy the conditions required by a payer in its contract with or on behalf of the covered member. The question then becomes how the obligations of the contract are met when a nonparticipating provider accepts the assignment of the benefit of payment?

28. One notable exception is a recent Georgia appeals court case, *Cox v. Athens Regional Medical Center*, A 06A0341 (Ga. App. 5-26-06). This case is another of the "charity care" cases that have been moving away from the federal courts and into the state systems. The appellate court denied relief to uninsured (but concededly not indigent) patients who claimed that the hospital's practice of charging uninsured patients more than it charged insured patients for the same procedures amounted to assorted violations of law and the hospital's fiduciary duty. The court held that Georgia does not recognize a fiduciary relationship between non-profit hospitals and uninsured patients with respect to pricing. It also said that the hospital was free under Georgia law to negotiate discounts with insurers in anticipation of increased volume, and that the patients' signature on agreements to pay the hospital's actual charges was legally binding. The admissions form containing the obligation did not set forth a dollar amount for services because the number could not be known in advance of treatment, the court observed. It also pointed out that the availability of chargemaster information gave the patients a way to determine the extent of their obligation and a choice in advance of securing the care. While the basic holding is sound, the failure of the court even to raise the issue of "reasonable value" is problematic. Other courts squarely have held that admission agreements are effectively contracts of adhesion, meaning that, as a practical matter, few patients presenting at a hospital have the opportunity to "shop around" or engage in an arms' length negotiation of an admission agreement. This court is silent on the issue, even though we are told that several of the plaintiffs required emergency procedures and all the plaintiffs had procedures that appeared not only to be medically necessary but of some urgency.

29. *Ellis Hospital v. Little*, 65 A.D.2d 644; 409 N.Y.S.2d 459 (3d Dept 1978).

30. *Kolari v. New York Presbyterian Hospital,* 382 F. Supp. 2d 562; 2005 U.S. Dist. LEXIS 4840 (one of the federal class action suits dismissed on its merits; see below); citing *Huntington Hospital v. Abrant,* 4 Misc. 3d 1, 779 N.Y.S.2d 891 (2d Dept 2004), *Albany Medical Center v. Huberty,* 76 A.D.2d 949, 428 N.Y.S.2d 746 (3d Dept 1980)).

31. *Temple University Hospital v. Healthcare Management Alternatives, Inc.*, 832 A. 2d 501 (Pa. Super. 2003).

32. *Valley Hospital v. Kroll*, 847 A. 2d 636 (NJ Super. 2003).

33. *Heartland Health Systems v. Chamberlin*, 871 S.W. 2d 8 (Mo. App. 1993).

34. If a hospital tries to follow the guidelines laid out by this court in determining the reasonableness of its rates by a close comparison of charges to those of other similarly situated hospitals in its own market area—assuming it accurately could determine what its competition is charging—how long will it be before some clever attorney also alleges that the hospital is violating anti-trust and anti-competition laws by unfairly "fixing" rates independent of its actual costs and business needs?

35. http://www.ins.state.ny.us/press/2008/p0808201.htm; *see, also*, http://www.ins.state.ny.us/hearing/oon_10072008/outnetagenda.pdf/.

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The Psychological and Behavioral Responses of Doctors to Malpractice Litigation

By Jeffrey Scott

When Dr. Daniel Merenstein was a third year medical resident, he saw a 53-year-old man for a physical examination. He discussed with his patient the risks and benefits of screening for prostate cancer and documented the discussion. Afterwards, the patient declined to take the test and Dr. Merenstein never saw him again. Sometime later, the patient saw a new doctor who ordered the prostate-specific antigen (PSA) test *without* discussing the risks and benefits of screening with the patient. Unfortunately for the patient, he was diagnosed with incurable, advanced prostate cancer. The patient sued Dr. Merenstein and the hospital where he did his residency. The plaintiff's attorney argued that Dr. Merenstein should never have discussed the risks and benefits of the PSA, and should have just ordered the test. Dr. Merenstein reflected in a journal article in 2004, "During that year before the trial, my patients became possible plaintiffs to me and I no longer discussed the risks and benefits of prostate cancer screening. I ordered more laboratory and radiological tests and simply referred more. My patients and I were the losers."[1] Dr. Merenstein's experience echoes the serious psychological and behavioral consequences when a physician goes through the process of malpractice litigation.

This research paper examines the impact of such litigation on physicians. It will explore the emotional and behavioral responses of physicians when they are sued for medical malpractice. Firstly, it will describe typical personality characteristics that shape how and why physicians react as they do when they are sued. This section will also explore the emotional responses among doctors as they go through the malpractice process. The second half of the paper will explore how, as a result of the fear of malpractice, doctors begin to practice "defensive medicine" by ordering excessive tests or procedures primarily to reduce liability.

The Personality Profile of the Physician

To understand how doctors respond to being sued, it is useful to consider typical personality characteristics which predispose them to act as they do.[2] Compulsiveness is the hallmark of the physician's personality.[3] Doubt, guilt feelings, and an exaggerated sense of responsibility seem to form a triad of compulsiveness that characterizes a physician's psychological makeup.[4] Physicians have these traits because a certain type of personality is drawn to the medical profession. As one study found, people may enter medicine as a way of dealing with an unconscious fear of death acquired during childhood.[5] This study also suggests that physicians may pursue medicine to keep from feeling helpless as well as to keep from hurting others.[6] There is often a secret omnipotence in the form of an overdeveloped expectation of one's self in the practice of medicine.[7]

In a study performed by Menninger Foundation, psychiatrist Glen Gabbard noted that, "whatever preexisting personality type may be attracted to the field of medicine, the process of medical education itself enhances and positively reinforces whatever preexisting compulsiveness is present. The stresses of medical school and residency foster the development of certain defense mechanisms that are typical of compulsive personalities."[8] Thus, the practice of medicine demands some compulsivity, and those attracted to the field are likely people who have these traits to begin with.[9]

The five principal characteristics of positive compulsiveness[10] found in most normal physicians are (1) responsibility and a preference to be in control, (2) conscientiousness and striving for excellence, (3) curious and independent thinking, (4) practical and pragmatic, and (5) dedicated to productivity and positive outcomes.[11] Although these characteristics allow doctors to perform well in their profession, those same traits can also lead to self destructive behaviors. As the Committee on Medical Liability of the American Academy of Pediatrics explains: "physicians tend to have high expectations of themselves and are consequently self-critical. When a physician is sued, however, their obsessive-compulsive personality traits generate self-doubt, self-scrutiny, feelings of guilt and shame, and often self-condemnation."[12]

These compulsive traits render physicians particularly vulnerable to the demands of tort law because fault must be established for compensation to be paid.[13] Physicians as a group are particularly sensitive to any suggestion that they have failed to meet the standard of care when they are being sued for medical malpractice. This accusation of failure represents a personal assault; this is the central psychological reaction to the event, which in turn generates stress and additional negative symptoms and behaviors.[14]

Emotional Responses

It is not uncommon for a physician to be sued for medical malpractice. According to one source, by 1997, there was nearly one suit for every five physicians in the United States.[15] If a doctor practices a high risk specialty, particularly in an urban area, the probability that he or she will be sued increases.[16] A national survey by *Medical Economics* journal found that 58 percent of the 1,800 physicians responding to its poll had been sued for malpractice,

and more than twenty percent of them had been sued at least three times.[17]

There have been reported psychological and emotional consequences for physicians as a result of being sued for malpractice. To be accused of negligence and actually sued for malpractice is an experience doctors often describe as "devastating."[18] The damage done to one's reputation, loss of patients, time taken away from a practice to consult with attorneys, depositions and court appearances, as well as financial expenses, can take a severe toll, regardless of the outcome.[19] An extensive study of the impact of malpractice litigation revealed that 96 percent of physicians suffered at least a temporary emotional disruption regardless of the court's decision.[20] In this study, doctors developed chronic emotional disturbances that included feelings of isolation, guilt, depression, and shame.[21] Moreover, a third of physicians involved in malpractice suits suffered from significant depression-manifested symptoms that included sadness, inner tension, insomnia, and fatigue.[22]

Physicians often perceive malpractice claims as a personal attack; this feeling may often manifest itself into anger and even rage. One study found that a quarter of physicians involved in malpractice suits admit to having such anger directed not only to the patient and to the legal and health care systems, but to themselves and family members.[23] Anger can be understood as an internal feeling and an external behavior.[24] Internally, anger often arises from the belief that one has been treated unfairly or trespassed upon in some way.[25] Externally, they may show behaviors that include rudeness, sarcasm, derogatory statements, or accusatory remarks and aggressive personal attacks.[26] Anyone associated with the doctor may be a target of his or her rage.

A male physician in 2004 described his feeling of anger as his malpractice case was readied for trial. He reflected:

> I felt violated. No matter how much venom I spewed about the faults of our malpractice system, the poison stayed within me. Who else would sue me now, I wondered? What if the next patient has an adverse effect from a medication I prescribed? What if the patient has an unfortunate outcome despite proper care? My rage at plaintiff's lawyers and the legal system went on unabated. Ultimately, I needed counseling to help me get through it. Only now, nearly two years later, am I finally ridding myself of the poison.[27]

Stress is another identifiable reaction to an accusation of medical negligence. One study of Chicago physicians reported that 57 percent of the total sample[28] acknowledged being part of one of two symptom groups: one cluster was characterized by a depressive disorder, and the other by pervasive anger accompanied by at least four of eight symptoms.[29] Thus, malpractice lawsuits have substantial emotional consequences for physicians involved.

With respect to a physician's emotional response to malpractice litigation, it is irrelevant whether or not he or she goes to trial, settles, or is found free of wrongdoing by the jury. More than 95 percent of sued physicians report experiencing periods of emotional distress during all or portions of the lengthy process of litigation.[30] Those who have been sued, regardless of the phase of litigation or the outcome of the suit, generally report significantly more adverse symptoms and changes in behavior than non-sued physicians.[31] One study found that the sued physicians reported significantly more severe depressed mood swings, inner tension, anger, and frustration than the non-sued physicians.[32]

Silence and Isolation

A physician's reluctance to speak about his or her malpractice lawsuit may ultimately contribute to depression and suicidal thoughts. Physicians may hide their claims either from shame, fear that his or her reputation will be damaged, or from attorneys' directives that instruct them not to discuss their case with others. Legal counsel may advise a physician not to talk about the details of the case because he or she may say something that will potentially jeopardize it.[33] Although this may be legitimate legal advice, it is not always conducive to meeting the doctor's psychological needs. Sharing the emotional impact of malpractice litigation with a colleague allows for a greater externalization of anger and may at the same time diminish the potential for turning that anger inward, a classic explanation for the development of symptoms of depression.[34]

Dr. George Hossfeld, a physician previously sued for malpractice, speculated that this type of litigation carries such a strong negative stigma that a doctor is inclined to hide it from coworkers, physician friends, and occasionally from his or her family.[35] This silence has an isolating effect that conflicts with proper ways of coping with stress.[36] It is this stress that causes anxiety, isolation, and helplessness, and has led some to suicide. Dr. Hossfeld proposes that physicians should openly discuss their malpractice lawsuits in order to overcome this negative stigma. He asserts, "enlightenment through exposure would go a long way in removing the stigma associated with its very name. The more we talk about it, the less the shame. Every opportunity to discuss our predicament should be an opportunity to expose it for what it is."[37]

The feelings of isolation may also vary depending upon whether the doctor is a sole defendant or accused as part of a group. Being accused as one of a group or in conjunction with a hospital may dilute the feelings of iso-

lation so commonly reported.[38] This may generate more anger but less depression.[39]

Dr. Joan Savitsky, a sole practitioner, described her psychological responses to being sued for malpractice in May of 2004. Legal action was taken against her by the children of her former patient who passed away from aggressive and undiagnosed colon cancer. Ultimately, the plaintiffs withdrew their case, but not before years of extensive litigation. The emotional toll on Dr. Savitsky was severe and catastrophic for her patients as well. Although she successfully defended herself, she closed her primary care practice of thirty years. Dr. Savitsky reflected on her experience:

> Medicine can be a minefield of uncertainties; no matter how thoughtful and careful we are, physiology is infinitely complex and fate is capricious, and occasionally something blows up in your face. If this happens, you have to integrate the experience, but for a while you lose your bearings. It is discombobulating. When this is followed by litigation, the effect can be paralyzing. And the lawsuit felt like an assault. Being sued, even with assurances that it's nothing personal and that my insurance would most likely cover any settlement was in fact deeply personal. The experience was devastating.[40]

Dr. Savitsky believed that being sued for malpractice was as if "a noxious subtle film had settled all around, making everything vaguely unfamiliar and unpleasant. I had become a little unfamiliar to myself. The film settled on everything at home and at work. I loved my patients and my practice, but this made me wary and mistrustful of them—and of myself."[41]

Dr. Savitsky's experience mirrored that of Dr. Hossfeld, who was previously discussed. The former isolated herself because of instructions from her attorneys not to discuss the details of her case to anyone but them. Dr. Savitsky contemplated maintaining a journal of the experience as a coping mechanism. However, her attorneys advised against this as well because of the possibility that it could be subpoenaed and used against her in court.[42] She was therefore unable to communicate her emotions with others or even to herself through the use of a journal.

Suicide

In the United States, doctors have the highest rate of suicide of any profession. During malpractice litigation, the pressure may be too great for some physicians who then opt to quit their practices; at the extreme, some may contemplate and even commit suicide.[43] Every year, between 300 and 400 physicians take their own lives. And, in sharp contrast to the general population, where male suicides outnumber female suicides four to one, the suicide rate among male and female doctors is the same.[44] Dr. Charles Reynolds, professor of psychiatry at the University of Pittsburgh School of Medicine, suspects that this high rate of suicide is a result of undiagnosed and untreated depression. Doctors are reluctant to seek help when they are feeling seriously depressed. They are used to helping others but resist seeking medical help for themselves, especially when they are dealing with an emotion-based condition.[45] A survey of Illinois physicians found that 90 percent of them suffered significant mental effects from the lawsuits, and ten percent of the doctors contemplated suicide.[46] Dr. John James and Dr. W. Edward Davis, in their book *Physicians Survival Guide to Litigation Stress*, cite a particularly poignant story in this regard:

> On Tuesday, November 25, 1986, a family practitioner felt so keenly dishonored and degraded by what he saw happening to himself that he killed himself. Nothing ambiguous, nothing vague, and absolutely and undeniably vivid. A man who was sensitive and intelligent is dead.[47]

Uncertainty

In addition to having fears of malpractice litigation, physicians develop stress over the uncertainty of medicine itself. As improvements are made in science and technology, ironically the awareness of risk and uncertainty increases proportionately.[48] The delivery of medical care is a "risky business," and even a prudent medical practitioner cannot be completely certain that his diagnosis or the therapy he prescribes is correct.[49] However, the lack of certainty and the existence of multiple schools of thought actually favor doctors in the courtroom. A doctor cannot be said to be negligent if he or she decides to defer to one school over another. In *Jones v. Chidester*, 610 A.2d 964 (Pa. 1992), the court held that where competent medical authority is divided, a physician will not be held responsible if in the exercise of his judgment he followed a course of treatment advocated by a considerable number of recognized and respected professionals in his given area of expertise.[50]

Despite this legal advantage, the lack of certainty is very disconcerting for doctors. Physicians have a fear or anxiety over bad outcomes resulting from either being wrong or uncertain about a medical diagnosis. There is a direct correlation between this fear of making an incorrect medical diagnosis and the prospect of a medical malpractice claim. One study found that physicians who perceived that their specialty encountered greater uncertainty reported significantly greater stress from uncertainty than physicians who perceived that their specialty encountered less uncertainty.[51] Fear or anger directed at the medical malpractice liability process is one possible response to uncertainty.[52]

Researchers who studied obstetrical care in British Columbia, Canada wrote an account of one physician who chose a non-interventionist approach to delivering a baby at the mother's request. Although he delivered a healthy baby, the doctor told the researchers that he knew there was no rational reason for him to be concerned about legal liability because the mother strongly agreed with his approach. However that knowledge did not eliminate his fear. What the doctor really feared was his own uncertainty about what the right thing to do was, and he also feared he would blame himself if something happened to the baby.[53]

Economic Implications

The consequences of malpractice liability and doctors' emotional responses to it have larger implications. Malpractice liability has directly affected physicians' labor market participation. A recent study explored the link between liability risk and physicians' hours of work.[54] The study shows that increases in liability decrease the number of hours a physician works. It found that doctors work 1.7 hours less per week when medical liability risk increases by ten percent. This decline in hours is the equivalent of one in every thirty-five physicians leaving the workforce entirely. The effect is strongest for physicians who are fifty-five or older, and the effect increases modestly with age.[55] Therefore, many physicians perceive a correlation between hours worked and the likelihood of malpractice lawsuits.[56] Doctors may also decline complex cases for fear of being sued. This combination of anxiety, and fear of liability, may result in the decline in hours worked, which may in turn, negatively impact patients' access to health care.

Freud's Psychoanalytical Theory

According to Freud, anxiety is the response to helplessness in the face of danger. If the danger has not yet occurred, anxiety is the anticipation of this helplessness.[57] The bodily changes from anxiety serve as a warning of the danger in the offing, and subsequently signal us to take action against the impending danger.[58] As Dr. Michael Kahn has identified, Freud divided anxiety into three categories: realistic, moral, and neurotic. Anxiety is a function of the ego, and the ego has three demanding forces: the external world, the id, and the superego.[59]

Freud's psychoanalytical perspective may be applied to a doctor's fear of a malpractice claim. Physicians may develop an overwhelming feeling of anxiety from the prospect of being sued. The uncertainty of medicine and its myriad of treatment choices, as well as the possibility of unforeseen complications, may cause a doctor to feel helpless and vulnerable in the face of malpractice lawsuits. The resulting financial, physical, emotional, and professional consequences of litigation are terrifying to physicians. Doctors may also suffer from the "realistic anxiety" manifested by the fear of receiving a summons for a malpractice claim. Doctors may also experience a "moral anxiety," which is a fear of being punished by the superego. It may manifest itself as doubt over whether a necessary medical test was not performed, a medication was not prescribed, or a diagnosis was overlooked. The result may be overwhelming guilt which may trigger physicians to perform extra tests to prevent such doubts in the future.

Part II—Defensive Medicine

Fear of being sued has led many physicians to practice *defensive medicine*. The Orthopedic Trauma Association says that *defensive medicine* occurs when doctors order excessive tests, procedures, and visits, or avoid high-risk patients or procedures, primarily to reduce their exposure to malpractice liability. When physicians order extra tests or order procedures primarily to reduce such a liability, they are practicing *positive* defensive medicine. When they avoid certain patients or procedures, they are practicing *negative* defensive medicine.[60] Concerns over liability are influencing medical decision-making on many levels. From the increased ordering of tests, medications, referrals, and procedures to increased paperwork and reluctance to provide off-duty medical assistance, the impact of the fear of litigation is far-reaching and profound.[61]

As previously mentioned, medical uncertainty has psychological effects on doctors. This uncertainty also contributes to the practice of defensive medicine. Concern about malpractice liability pushes physicians' tolerance for uncertainty about medical outcomes to very low levels.[62] The high rate of unnecessary surgeries and prescriptions, for example, bears testimony to physicians' propensity to resolve uncertainty and ambiguity by action rather than inaction.[63] The increased ordering of tests strives for diagnostic certainty rather than pragmatic decisions about treatment.[64]

Defensive medicine is common practice.[65] One study found that 90 percent of physicians surveyed admitted to using defensive medicine.[66] Another study, conducted by the Medical Society of Massachusetts physicians last year, found that 83 percent of physicians reported practicing defensive medicine, and that an average of 18 to 28 percent of tests, procedures, referrals and consultations and 13 percent of hospitalizations were ordered for defensive reasons. Amitabh Chandra of Harvard University conservatively estimates the annual cost of defensive medicine at 60 billion dollars. Other research places the yearly cost at roughly 200 billion dollars.[67]

The Emergency Room

Emergency room physicians worry about malpractice much of the time. Consequently, defensive medicine is used there extensively. The emergency room is one of the most stressful worksites in the health care profession. According to Dr. Leon Phipps, emergency department

personnel work in a charged atmosphere that is overloaded with sensory stimuli (ringing phones, rushing people, beeping monitors), all in a framework of urgency that may change dramatically from one minute to the next.[68] Emergency department staff must continually distinguish between patients who are simply worried, those who have minor illnesses, those who are candidates for sudden deterioration and those who are critically ill. Decisions are not easily reversible. The fear of making an irrevocable mistake is always present.[69]

Many claims are filed against personnel in the emergency room because of an alleged failure to diagnose an impending calamity, to provide treatment quickly, or, where a patient is turned down by emergency room personnel.[70] *Time* magazine's article "Medicine: do you want to die?" published in 1990, describes the influence of medical malpractice fears in the setting of an emergency room. It quoted one physician who stated, "In the E.R. you're a sitting duck for malpractice, and people here know it. For all their heroic efforts, emergency room doctors have little chance to establish a continuing relationship with patients and little time for tenderness."[71] The physician further stated, "the waits can be long, the treatments painful and the sheer volume of patients high. You have to work quickly during an emergency with a lot of angry people, in a climate in which lawsuits are used by people to express their anger."[72]

As a result of the emergency room environment, many doctors resort to defensive medicine in order to protect themselves from potential malpractice lawsuits. A 2005 study found that emergency physicians who have the greatest fear of being sued for malpractice are more likely to order tests for patients with chest pain or other heart symptoms, even if those patients are at low risk for actual problems.[73]

Blogs

Today, blogs have become a common way for physicians to anonymously provide commentary on health care, as well as to vent emotionally. As previously discussed, medical malpractice carries such a strong negative stigma that doctors are hesitant to discuss their own experiences openly. The anonymity of a blog allows doctors to be more candid and uninhibited; it provides doctors with an avenue for self expression. Similarly, doctors who read the blogs can identify with, support, and share their own experiences.

Blogs have been very outspoken about the subject of defensive medicine. The *Happy Hospitalist,* a popular blog in the medical community, expressed its views on defensive medicine:

> And you wonder why doctors order lots of tests. Some doctors and patients may be willing to experience some anxiety for the unknown. But most won't, especially since neither party is directly paying for the testing.
>
> Thus is the nature of defensive medicine. A stealth tax that we all pay for in unaffordable premiums and reduced wages. Those that claim it doesn't exist need only look to the four box theory below to understand why it's alive and well in America. Most doctors are not going to sacrifice their self interests for the common economic good especially when the only alternative to cheaper care and good outcomes is cheaper care and losing your home.[74]

The *White Coat's Call Room* is another blog that has gained popularity in the medical community for its fresh approach to physicians' emotional responses to the fear of malpractice. The writer of this blog is an anonymous emergency room doctor who has written several pieces on defensive medicine. In one such article he described a study he performed on himself as to whether he used defensive medicine on a given day. The writer reflected:

> By the end of the shift, I was getting annoyed with myself because I kept second-guessing my decisions to order tests that would most likely be normal. Why was I ordering all of these things when my clinical judgment led me to believe that they would "probably" not lead to any changes in the patient's management?
>
> The answer is because in our culture, "probably" doesn't cut the mustard any more. Clinical medical judgment has been supplanted by the demand that physicians disprove the improbable. Society has made it so that physicians are more concerned with proving that unlikely diagnoses with the possibility of a "bad outcome" don't exist and with maintaining good Press Ganey scores. Many physicians are afraid to practice rational medicine based upon clinical judgment and physical examination skills. No one wants to face the liability.
>
> You know and I know that had I missed anything, I would either be explaining myself to hospital administration when the patient complained about paying the bill for the "dumb doctor" that didn't diagnose the problem or that I would be spending the next several years listening to a plaintiff's attorney telling everyone how the patient's injury is an example of why I am a bad doctor and why clinical

examination alone is simply not good enough.

That, my friends, is defensive medicine at work.[75]

Fear of liability is cited by physicians and hospital administrators as the leading factor that discourages medical professionals from openly discussing and thinking of ways to reduce medical errors that lead to malpractice suits.[76] Although hospital administrators may disagree, physicians feel that fear of liability often causes hospitals to avoid disclosing quality deficiencies and is the primary reason why hospitals do not share the results of inquiries into patient injury cases.[77] Dialogue is needed in order to effectuate change. However, the fear of liability prevents members of the medical community from conducting open discussions. Anonymous blogs have become an attractive avenue for physicians to express their views without fear of liability. Therefore, blogs are playing an important role in the medical community that so often avoids any discussion of medical malpractice.

The Effects on Medical School Training

Medical school professors and clinical physicians are also cognizant of malpractice lawsuits and their psychological ramifications, and have adjusted their teaching style accordingly. According to a Mayo Clinic study, medical malpractice is prominently positioned in the consciousness of American physicians, and the perceived threat of malpractice litigation may push physicians to practice defensively and alter their teaching behaviors.[78] The Mayo Clinic surveyed 200 full-time clinically active physicians in the Department of Medicine at a large academic medical center. Faculty reported that because of the perceived prevalence of lawsuits and claims made against physicians, 74 percent of them spend more time writing clinical notes for patients seen by students. That gives students less autonomy in patient care, and limits the opportunities for them to perform clinical procedures, as well as deliver bad news to patients.[79] The researchers concluded that these results may serve to heighten awareness of the fact that teaching behaviors may be influenced by the malpractice climate.[80]

Conclusion

This paper explored the emotional impact of malpractice litigation on doctors. It revealed how common personality characteristics directly contribute to the emotional and behavioral responses that physicians exhibit towards malpractice litigation. These emotional responses include feelings of anxiety, shame, stress, and depression. During and following litigation, a considerable amount of physicians have contemplated or committed suicide because of untreated depression, forced silence, and self-imposed isolation.

The fear of malpractice liability among physicians has also resulted in the practice of defensive medicine. The impact of the fear of litigation is far-reaching and profound. Some estimates place the yearly cost of defensive medicine at roughly 200 billion dollars. Another negative effect of the psychological fallout from malpractice proceedings is the decline in patient access to health care when doctors cut their hours. In addition, negativity and anxiety may corrupt medical school training of future doctors. It is also more difficult to address medical errors when there is a lack of dialogue in the physician community regarding such errors and ways to avoid them in the future. However, change is coming slowly as more doctors are communicating their experiences and views through the use of blogs and other means of self-expression.

References

- Anonymous, Behavior; *Research from Mayo Clinic in the Area of Behavior Published*, Hospital Law Weekly (2008) at 51.
- Anonymous, *Stress in Physicians, A Deadly Dilemma*, Health and Stress, Oct. 2007, at 1, 11, *available at* http://0-proquest.umi.com.ben.bc.yu.edu:80/pqdweb?did=1357457911&sid=4&Fmt=3&clientId=68805&RQT=309&VName=PQD.
- Tom Baker, The Medical Malpractice Myth, 17 (2005).
- Sara C. Charles, M.D. et al., *Sued and Nonsued Physicians' Self-Reported Reactions to Malpractice Litigation,* 142 Am. J. Psychiatry 437, 438 (1985).
- Sara C. Charles, M.D. et al., *Physicians on Trial–Self-Reported Reactions to Malpractice Trials*, 148 West J. Med 358, 359 (1988).
- Sara C. Charles, *Coping with a Medical Malpractice Suit*, 174 West J. Med 55 (2001).
- *Jones v. Chidester*, 531 Pa. 31, 610 A.2d 964 (Pa. 1992).
- *Common Good Fear of Litigation Study: The Impact of Medicine*, The Common Good (2002).
- *Defensive Medicine and Medical Malpractice*, Office of Technology Assessment, Congress of the United States (1994).
- *Defensive Medicine at Work*, http://www.epmonthly.com/whitecoat/2009/01/defensive-medicine-at-work/ (last visited February 18, 2010).
- Jason D. Fodeman, M.D., *Defensive Medicine Costs*, The Washington Times, November 29, 2009.
- Glen O. Gabbard, M.D., *The Role of Compulsiveness in the Normal Physician*, 254 JAMA 2926, 2927 (1985).

- Martha S. Gerrity, et al., *Uncertainty and Professional Work: Perceptions of Physicians in Clinical Practice*, 97 AJS 1022, 1023, 1029, 1039 (1992).
- Jody Gloor, *Support Medical Tort Reform, Use Risk Management,* 8 FPReport 6 (2006).
- Eric Helland, et al., *The Impact of Liability on the Physician Labor Market*, 52 The Journal of Law and Economics 636-663, 665 (2009).
- George Hossfeld, M.D., *Speak the Unspeakable: 'I Was Sued for Malpractice*,' 31 Emergency Medicine News 1, 3, 15 (2009).
- *Impact of Legal Reforms on Medical Malpractice Costs*, Office ofTechnology Assessment (1993).
- John M. James, *Physicians Survival Guide to Litigation Stress*, 9, 15, 16, 31, 33, 34, 37, 42, 45, 46, 47, 48, 54, 62 (2006).
- Michael Kahn, Ph.D., *Basic Freud: Psychoanalytic Thought for the 21st Century*, 108, 112 (2002).
- David Katz, *Medical Malpractice; Fear of lawsuits affects emergency physicians' heart care decisions*, Heart Disease Weekly at 212 (2005).
- Jerry Kremer, *Malpractice Fears have Doctors Worried Sick*, L.I. Business News, July 25, 2008.
- *Medicine: Do you want to die*?, Time, May 28, 1990, *available at* http://www.time.com/time/magazine/article/0,9171,970208-1,00.html.
- Daniel Merenstein, M.D., *Winners and Losers*, 291 JAMA 15 (2004).
- David Noonan, *Doctors Who Kill Themselves*, Newsweek, Apr. 28, 2008.
- Steven E. Pegalis, et al., *American Law of Medical Malpractice*, 1:1 to 5:18 The Lawyers Co-operative Publishing Company (1980).
- Leon Phipps, M.D., *Stress Among Doctors and Nurses in the Emergency Department of a General Hospital*, 139 CMAJ, 375 (1988).
- Poll, Harris Interactive, Inc., *The Fear of Litigation Study—The Impact on Medicine*, 39 (2002), *available at* http://cgood.org/healthcare-reading-cgpubs-polls-6.html.
- Simon Rottenberg, *The Economics of Medical Malpractice* (1978).
- Joan Savitsky, *A Patient Dies, and Then the Anguish of Litigation*, N.Y. Times, December 28, 2009, at D5.
- Frank A. Sloan, *Suing for Medical Malpractice*, 8 (1993).
- David M. Studdert, et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 21 (2005).
- U.S. Congress, Office of Technology Assessment, Impact of Legal Reforms on Medical Malpractice Costs, OTA-BP-H-1 19 (1993).
- What Is Defensive Medicine?, http://thehappyhospitalist.blogspot.com/2009/09/what-is-defensive-medicine.html (last visited February 21, 2010).

Endnotes

1. Daniel Merenstein, M.D., *Winners and Losers*, 291 JAMA 15 (2004).
2. John M. James, *Physicians Survival Guide to Litigation Stress*, 31 (1st ed., Physician Health Publication 2006).
3. Glen O. Gabbard, M.D., *The Role of Compulsiveness in the Normal Physician*, 254 JAMA 2926 (1985).
4. *Id.*
5. *Id.* at 2927.
6. *Id.*
7. *Id.*
8. *Id.*
9. James, *supra* note 2, at 33.
10. James, *supra* note 2, at 34. The author points out that the word "compulsive" sometimes carries negative connotations. Here, however, compulsiveness has a positive connotation: that being, "a strong urge, drive, or conviction to achieve desired results."*Id.*
11. James, *supra* note 2, at 37.
12. James, *supra* note 2, at 42.
13. Sara C. Charles, *Coping with a Medical Malpractice Suit*, 174 West J. Med 55 (2001).
14. *Id.* at 55.
15. See James, *supra* note 2, at 9 (citing Anderson RE., *Outcomes of Medical-Malpractice Litigation*, 336 New England Journal of Medicine 1680-1681 (1997)).
16. Sara C. Charles, M.D. et al., *Sued and Nonsued Physicians' Self-Reported Reactions to Malpractice Litigation,* 142 Am. J. Psychiatry 437 (1985).
17. James, *supra* note 2, at 9 (citing Mark Crane, *Our National Survey Confirms: Even the Best Doctors are Targets,* 76 Medical Economics 11-17 (1999).
18. Anonymous, *Stress in Physicians, A Deadly Dilemma*, Health and Stress, Oct. 2007, at 1, 11, *available at* http://0-proquest.umi.com.ben.bc.yu.edu:80/pqdweb?did=1357457911&sid=4&Fmt=3&clientId=68805&RQT=309&VName=PQD.
19. *Id.*
20. *Id.*
21. *Id.* The authors also noted that some of the most common immediate responses included: "a blow, personally and professionally"; "I felt stunned, shocked, and frightened"; "I felt embarrassed"; "I got angry when it finally settled in. Why are they doing this to me?" *See id.*
22. *Id.*
23. *See* Anonymous, *supra* note 18.
24. James, *supra* note 2, at 47-48. This is often accompanied by racing thoughts and difficulty concentrating. Associated physiological symptoms can include increased heart rate, rapid breathing, agitation and hyper arousal, and tension in the jaw, shoulders, or stomach. *See id.* at 45.
25. *Id.*
26. *Id.*

27. James, *supra* note 2, at 46 (citing M. Lopatin, *Malpractice: I Knew She was Trouble*. 81 Medical Economics 39 (2004)).
28. The Chicago Medical Society sent to one thousand physicians randomly selected from its exclusive member list. It had a response rate of 36.6 percent. *See* Charles *supra* note 16, at 437.
29. These eight symptoms include depressed mood, inner tension, frustration, irritability, insomnia, fatigue, gastrointestinal symptoms, or headache. *See* Charles *supra* note 16, at 438.
30. Common post complaint experiences include: (1) when complaint is served, initial feelings of surprise, shock, outrage, anxiety, or dread; (2) when consultation with lawyer: reactions of anger, denial, concern, reassurance, panic; (3) lengthy period of denials and intrusions: active attempts to erase thoughts about the case, followed by automatic reminders and intrusive thoughts about it. *See* Charles, *supra* note 13, at 55.
31. Sara C. Charles, M.D. et al., *Physicians on Trial—Self-Reported Reactions to Malpractice Trials*, 148 West J. Med 358, 359 (1988).
32. *Id.* at 359.
33. Charles, *supra* note 13, at 55.
34. Charles, *supra* note 31, at 360.
35. George Hossfeld, M.D., *Speak the Unspeakable: 'I Was Sued for Malpractice*,' 31 Emergency Medicine News 3, 16 (2009).
36. The resultant loss of substantial social support, which is a powerful stress buster, can significantly reduce resistance to disease. *See* Anonymous, *supra* note 18.
37. Hossfeld, *supra* note 35, at 16 (2009).
38. Charles, *supra* note 31 at 359.
39. *Id.*
40. Joan Savitsky, *A Patient Dies, and Then the Anguish of Litigation*, N.Y. Times, December 28, 2009, at D5.
41. *Id.*
42. *Id.*
43. James, *supra* note 2, at 54.
44. David Noonan, *Doctors Who Kill Themselves*, Newsweek, Apr. 28, 2008.
45. James, *supra* note 2, at 62.
46. Jody Gloor, *Support Medical Tort Reform, Use Risk Management*, 8 FPReport 6 (2006). AAFP Board Chair Richard Roberts, M.D., J.D., of Madison, Wisconsin conducted the study of 220 Cook County, Ill., physicians who had fought medical liability case. *See id.*
47. James, *supra* note 2, at 15-16.
48. Martha S. Gerrity, et al., *Uncertainty and Professional Work: Perceptions of Physicians in Clinical Practice*, 97 AJS 1022, 1023 (1992).
49. *See* Simon Rottenberg, *The Economics of Medical Malpractice* (American Enterprise Institute for Public Policy Research 1978).
50. *Jones v. Chidester*, 531 Pa. 31, 610 A.2d 964 (Pa. 1992).
51. Gerrity, *supra* note 48, at 1039.
52. Tom Baker, *The Medical Malpractice Myth*, 17 (University of Chicago Press 2005).
53. *Id.* (citing Basset et al. 2000 at 528).
54. Eric Helland, et al., *The Impact of Liability on the Physician Labor Market*, 52 The Journal of Law and Economics 636-663 (2009).
55. *Id*. at 655.
56. *See* Jerry Kremer, *Malpractice Fears have Doctor's Worried Sick*, L.I. Business News, July 25, 2008. High insurance premiums are also responsible for doctors to prematurely retire because of their inability to make the premium payments. *Id.*
57. Michael Kahn, Ph.D., *Basic Freud: Psychoanalytic Thought for the 21st Century*, 108 (1st ed. Basic Books 2002).
58. *Id.*
59. *Id. at* 112.
60. *Defensive Medicine and Medical Malpractice*, Office of Technology Assessment (1994), *available at* http://biotech.law.lsu.edu/policy/9405.pdf.
61. Poll, Harris Interactive, Inc., *The Fear of Litigation Study–The Impact on Medicine*, 8 (2002), *available at* http://cgood.org/healthcare-reading-cgpubs-polls-6.html.
62. *Defensive Medicine and Medical Malpractice*, Office of Technology Assessment (1994).
63. Gerrity, *supra* note 48, at 1029.
64. *Id.*
65. Defensive medicine is widespread, but according to the Judicial Counsel of the AMA, "it is unethical for a physician to provide or prescribe unnecessary services or unnecessary ancillary facilities." Steven E. Pegalis, et al., *American Law of Medical Malpractice*, 1:1 to 5:18 The Lawyers Co-operative Publishing Company (1980).
66. David M. Studdert, et al., *Defensive Medicine Among High-Risk Specialist Physicians in a Volatile Malpractice Environment*, 293 JAMA 21 (2005).
67. Jason D. Fodeman, M.D., *Defensive Medicine Costs*, The Washington Times, November 29, 2009. *Impact of Legal Reforms on Medical Malpractice Costs*, Office of Technology Assessment (1993) *available at* http://www.fas.org/ota/reports/9329.pdf. It should also be noted though that it is difficult to measure the extent of defensive medicine because the effect of malpractice can work through subtle avenues, including the incorporation of defensive practices into physicians' training. *Id.*
68. Leon Phipps, M.D., *Stress Among Doctors and Nurses in the Emergency Department of a General Hospital*, 139 CMAJ, 375 (1988).
69. *Id.*
70. Frank A. Sloan, *Suing for Medical Malpractice*, 8 (1st ed., University of Chicago Press 1993).
71. *Medicine: Do you want to die*?, Time, May 28, 1990, *available at* http://www.time.com/time/magazinearticle/0,9171,970208-1,00.html.
72. *Id.*
73. These findings were based on surveys of 33 emergency doctors who participated in a prospective study of 1134 patients at two teaching hospitals. The results appear in the Annals of Emergency Medicine. David Katz, *Medical Malpractice; Fear of lawsuits affects emergency physicians' heart care decisions,* Heart Disease Weekly at 212 (2005).
74. *What Is Defensive Medicine?*, http://thehappyhospitalist.blogspot.com/2009/09/what-is-defensive-medicine.html (last visited February 21, 2010).
75. *Defensive Medicine At Work*, http://www.epmonthly.com/whitecoat/2009/01/defensive-medicine-at-work/ (last visited February 18, 2010).
76. *Common Good Fear of Litigation Study: The Impact of Medicine*, The Common Good (2002), *available at* http://commongood.org/assets/attachments/68.pdf.
77. *Id.*
78. Anonymous, *Behavior; Research from Mayo Clinic in the Area of Behavior Published*, Hospital Law Weekly (2008) at 51.
79. *Id.*
80. *Id.*

Jeff Scott recently graduated from Benjamin N. Cardozo School of Law. He received his undergraduate degree from SUNY Binghamton. Mr. Scott currently lives in Syosett, NY.

NEWS flash

What's Happening in the Section

Ari J. Markenson Becomes Section Chair

Ari J. Markenson of White Plains (Benesch Friedlander Coplan & Aronoff LLP) is the new Chair of the Health Law Section.

Markenson received his undergraduate degree from Syracuse University, and earned his law degree from Brooklyn Law School. Markenson also received a master's degree from Columbia University School of Public Health.

Markenson is of counsel to Benesch Friedlander Coplan & Aronoff LLP's National Healthcare Practice Group, providing counsel to various health care industry clients, including providers and payers on a wide range of matters with a concentration and specific expertise in the representation of post–acute care providers.

An active member of the Health Law Section, Markenson is the youngest member to ever Chair the Section. He previously chaired the section's Committee on Long-Term Care and is a member of the Committee on Fraud, Abuse and Compliance.

Markenson also is active in the American Bar Association, the American Health Lawyers Association, the American Health Care Association, the Association of Corporate Counsel, and the District of Columbia Bar. Markenson was recognized as an "Outstanding Young Health Care Lawyer" by Nightingale's Healthcare News in 2004.

Markenson is an adjunct associate professor at the University of Maryland University College, Graduate School of Management and Technology, and a lecturer at the School of Health Sciences and Practice, New York Medical College.

Recent Events

- **Health Law Fundamentals.** The Section and the NYSBA CLE Committee conducted a program on Health Law Fundamentals on April 9 in NYC and on April 16 in Albany. Topics covered included fundamentals of reimbursement, conditions of participation and operating regulations, HIPAA and confidentiality of health information, health care decision making, fraud and abuse, and regulatory compliance. The Overall Planning Chair and NYC Chair was Ari J. Markenson, J.D., M.P.H. of Benesch Friedlander Coplan & Aronoff LLP (White Plains). The Albany Chair was Martin Bienstock of Wilson Elser Moskowitz Edelman & Dicker, LLP (Albany).
- **2010 Long Term Care Conference.** This program, sponsored by the Section and the NYSBA CLE Committee, focused on current trends, government initiatives and practical issues faced by this segment of the industry. The program also included a panel discussion on the future legal issues regarding quality of care. Experts in the field discussed current challenges facing the long-term care industry. The program was offered in Buffalo on May 7, NYC on May 14 and Albany on May 21. The Overall Planning Chair was Richard T. Yarmel, Esq. of Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP (Rochester). The Local Planning Chairs were Ellen V. Weissman, Esq. of Hodgson Russ LLP (Buffalo), Patrick Formato, Esq. of Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP (Lake Success) and Raul A. Tabora, Jr., Esq. of Ruffo Tabora Mainello & McKay PC (Albany).

Save These Dates

- **Health Law Section Fall Meeting**. The Section will hold its Executive Committee Meeting on Friday, October 22, 2010 and its Fall Meeting Program on Saturday, October 23, 2010. The meeting will be at the Equinox Hotel in Manchester, VT. The program is being developed and more information will be available soon on the Section's website. But the meeting will include time to enjoy the beautiful New England fall foliage.

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

Health Law Section's "State Stark Law" Proposal Introduced

A state legislative proposal developed by the Health Law Section's "State Stark Law Task Force" has been introduced in both the NYS Senate and Assembly by the chairs of the respective Health Committees. The bills, S.6955 (Duane) and A.9933 (Gottfried) would amend NY's law prohibiting certain self-referrals by health care practitioners (NY Pub. Health L. §238-a), to incorporate by reference the exceptions in the federal prohibition on self-referrals by physicians. The Section's State Stark Law Task Force is headed by Marcia Smith of Iseman, Cunningham, Riester & Hyde in Albany.

Family Health Care Decisions Act Information Center

The Section recently launched a web-based resource center designed to help New Yorkers understand new rules allowing family members to make critical health care and end-of-life decisions for patients who are unable to make their wishes known. The Family Health Care Decisions Act Information Center provides the public, health care professionals, advocates and lawmakers with up-to-date information regarding the new Family Health Care Decisions Act (FHCDA) that took effect on June 1, 2010.

The FHCDA Information Center Web page, located at www.nysba.org/fhcda, contains a wealth of important information, including the law's complete text, summaries of its key provisions, articles covering a wide variety of related topics, and materials from the New York State Department of Health. A frequently asked questions (FAQ) section edited by experts will provide guidance about the new law. The Web page will also include a listserve to promote the exchange of information about the new law.

"This new Information Center will be a critically important resource that can help families make informed medical decisions about the proper care of their loved ones," said State Bar Association President Stephen P. Younger. "I want to thank the members of the Health Law Section, including past chairs Robert Swidler and Ed Kornreich, for their outstanding work in creating such an invaluable tool and helping facilitate the swift implementation of this new law."

The members of the Editorial Board of the FHCDA Information Center are:

- **Kathy Faber-Langendoen, MD,** Medical Alumni Endowed Professor of Bioethics and Professor of Medicine, SUNY Upstate Medical University, Syracuse, NY
- **Jack P. Freer, MD**, Professor of Medicine, University at Buffalo and Kaleida Health, Medical Director, Ethics, Buffalo, NY
- **Hon. Richard N. Gottfried**, Chair, NYS Assembly Health Committee
- **Jonathan Karmel, Esq**., Attorney, NYS Department of Health, Albany NY
- **Deborah Korzenik, Esq**., Senior Associate General Counsel, Continuum Health Partners, Inc., NYC
- **Tracy E. Miller, Esq.**, President, Health Policy and Education Initiatives, LLC, former Executive Director, NYS Task Force on Life and the Law
- **Salvatore J. Russo, Esq.**, General Counsel (Acting), NYC Health and Hospitals Corporation, NYC
- **Robert N. Swidler, Esq.**, General Counsel, Northeast Health, Troy NY

Recent Supraspinatus Topics

- Threat of HIPAA "Jail Time" Now Real
- HHS Creates Office of Consumer Information and Insurance Oversight
- DOH Announces $18.5 Million in Workforce Retraining Grants
- DOH: New York Hospitals Weakest in the Nation
- Improving Access to Innovative Medical Therapies: new law
- Recent Legislative Activity
- Insurance Department Proposes "Discretionary Clauses" Regulation
- Pres. Obama's Choices for New Bioethics Commission
- Is That Doctor a Doctor Doctor or Doctor-Nurse Doctor?
- NYAG Recovers $283 Million in 2009 With 148 Criminal Fraud Convictions
- St. Vincent's to Close
- Health Reform-related proposed Constitutional amendment introduced
- Court of Appeals Refuses OMH Record Request
- BRCA1/2 patents ruled invalid in PUBPAT/ACLU lawsuit
- Recess begins, signaling late budget
- Houses announce individual Budget positions
- New NYLJ Article: "Personal Liability of Hospital Board Members, Executives for Unpaid Taxes"
- Family Health Care Decisions Act—A Long Road Ends in Success
- FHCDA Signed today

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 (listed on the back page) or Committee Chairs for further information about these Committees.

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For more information on these and many other resources go to **www.nysba.org**

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Save the Date

HEALTH LAW SECTION

FALL MEETING

October 23, 2010

The Equinox
Manchester, VT