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Health Law Journal

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

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- The 21st Century Cures Act
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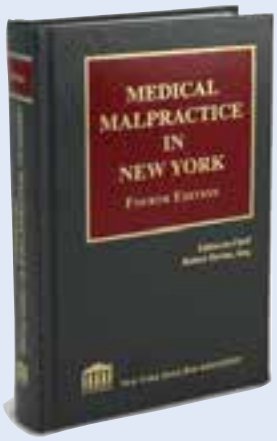

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HEALTH LAW JOURNAL

Spring 2017

Vol. 22, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork: *Garden at Sainte-Adresse,* Claude Monet, 1867

Message from the Chair

Our Section has recently established a Special Committee to examine issues associated with the upcoming vote on whether to hold a State Constitutional Convention, to be on the ballot in the next general election. The stakes are high. A potential issue is whether our state should adopt an indelible right to health care. We have always looked at the grand experiment of the United States as being unique in the world. What makes our country so unique are the structures we have inherited from the Founders, which not only gave us a national Bill of Rights but reserved to each state the ability to expand upon such rights.

The Special Committee on the State Constitutional Convention–Focus on Health is being co-chaired by Nathan Prystowsky and Hermes Fernandez. In addition, many of the highly experienced and knowledgeable members of our Section's Executive Committee have volunteered to assist with the Special Committee's agenda. This agenda will be focused on what our Section should recommend for the upcoming vote as well as prepare for the possibility that a convention may actually be convened. Given the importance of health care and the need to ensure proper coverage of populations that are unprotected or at risk, the Special Committee may assist not only in arriving at recommendations but also examine other issues which may impact health in this state.

Additional background is available on the NYSBA website,[1] which shows that the Committee on the State Constitutional Convention has been working diligently to examine a variety of different issues. This Committee, headed by former Chair of our Section, Henry Greenberg, has issued reports on "The Judiciary Article of the New York State Constitution: Opportunities to Restructure and Modernize the New York Courts," and the state's "Home Rule" provision, which deals with relative powers of the state and local governments as well as the Conservation Article, which includes a "forever wild" provision impacting wilderness areas of the state. [2] Our Association has also published a print and e-book entitled *Making a Modern Constitution* which provides an in-depth assessment of the history of the State's Constitution and devotes a segment involving decisions regarding the health care needs of the poor. (See particularly the chapter on "Positive Rights in the New York State Constitution" at pages 180 to 191.)[3]

As explained in *Making a Modern Constitution*, the so-called "social welfare article[4] was established so that there would be no doubt involving care to the needy and to "set[ting] down explicitly in our basic law a much needed definition of the relationship of the people to their government." *Id*. at page 181. This Article provides at § 1 that the "*aid, care and support of the needy* are public concerns and *shall be provided by the state and by such of its subdivisions*, and *in such manner and by such means, as the legislature may from time to time determine*" (emphasis supplied).

This "was one of several progressive measures adopted at the 1938 constitutional convention aimed at strengthening state support for the economically disadvantaged." (*Id*.) Several decisions involving Medicaid benefits and other benefit programs have given this article some vitality. In the area of Medicaid, the Court of Appeals considered the application of this "positive right" to the health care needs of undocumented aliens.[5] New York denied coverage to a category of such aliens, including those who were "permanently residing under color of law" (PRUCOL). The Court held that this violated "the letter and spirit of article XVII,…by imposing on plaintiffs an…eligibility condition having nothing to do with need." This decision may have increased resonance as we continue to see health care on the public policy agenda.

Given the recent initiatives to further diminish Federal Medicaid coverage and restructure this statute from an entitlement program to a block grant for states, new issues will be raised as to New York's role in this arena. It would be appropriate for the current generation of New Yorkers to review concepts which will not only impact them today but potentially for many future generations. Is there a need for re-examination of the standard set for the needy? Should the citizens of New York establish further protections beyond the needy? Should there be a positive right to access or universal health care which is not based on need? The Court of Appeals has thus far limited the existing social welfare mandate to denials of access as applied to classes of individuals based on need. Should the mandate also extend to basic health care coverage?

In this regard, several other sections of the New York State Constitution focus on "public health" and treatments for those suffering from "mental disorders or defect."[6] The section on public health provides that (t)he protection and promotion of the health *of the inhabitants of the state* are matters of public concern and provision therefor shall be made by the state and by such of its subdivisions and in such manner, and by such means as the legislature shall from time to time determine" (emphasis supplied). Commentators in this area have argued that when "(t)aken together, the text, structure, purpose, and history of the provision make clear that it includes a guarantee of adequate health care as essential to safeguarding

the public's health."[7] They point to the arguments of the day during the 1938 Convention, quoting a presentation by then-New York State Health Commissioner Dr. Edward S. Godfrey, where he states: "Care must be taken to make sure that new plans [for the extension of medical services] will work well, at a reasonable cost to the public.... Today, no physician would go back to the old days when the needy were left to fend for themselves medically."[8]

These are important concepts if there is a belief and consensus in progress and advancement of society. To a certain extent, however, the belief that citizens in a constitutional government have a duty to provide for the health of all individuals has existed without question in our history. Over 20 years ago I found a used book while vacationing in Maine entitled simply, *A. Lincoln, Prairie Lawyer*" (published 1960). It was written by a lawyer in NYC—John Duff—who had gone through original documents still on file as of the 1950s within the courthouses and clerk's offices where Lincoln tried cases throughout Illinois. In this book there is a copy of a legal opinion written by Lincoln on the question of who should bear the costs of medical expenses for a destitute immigrant Irishman—found in the streets of City of Springfield within the County of Sangamon and aided by a physician as a "public charge." The physician was seeking payment for his services and Lincoln was asked to study the charters and opine on who should pay—the city or the county? Lincoln relied on the constitution and charters of the time which provided that "all public charges arising from the indigence of persons *resident* within the City" would be paid by the city. (See Opinion of Lincoln, dated December 18, 1854.)

Interestingly, in 1854 the question was not whether essential care would be met but rather which governmental body would pay for such needs. We look forward to the work of our Special Committee on these issues in the coming months.

Raul A. Tabora, Jr.

Endnotes

1. www.nysba.org/CustomTemplates/SecondaryStandard.aspx?id=71177.
2. www.nysba.org/ArticleXIVreport.
3. www.nysba.org/ConConBook/ to download this e-book.
4. NYS Constitution Article XVII.
5. See *Aliessa v. Novello*, 96 N.Y.2d 418 (2001).
6. Sections 3 and 4 of Article VII.
7. Alan Jenkins & Sabrineh Ardalan, *Positive Health: The Human Right to Health Care Under the New York State Constitution,* 35 Fordham Urb. L.J. 479, 486 (2008).
8. *Id*. at 489.

In the New York State Courts

By Leonard M. Rosenberg

Second Circuit Court of Appeals Holds That Pharmacist With Fear of Needles Has No Claim Under the ADA

Stevens v. Rite Aid, 2017 WL 1055566 (2d Cir. 3/21/2017). Plaintiff was employed by Rite Aid as a pharmacist. When Rite Aid introduced a program to provide immunization shots to customers, it changed the pharmacist job description to require immunization certification, and added administering immunizations to the list of essential job functions. Plaintiff suffered from trypanophobia—fear of needles—and provided a physician's note stating that he could not safely administer immunization by injection because he would likely begin sweating profusely, suffer low blood pressure, and faint. Rite Aid terminated plaintiff's employment, and he sued under the Americans with Disabilities Act. After a jury awarded plaintiff $2.6 million in damages, the Circuit Court held that giving immunizations was an essential job function. Because plaintiff could not perform the essential function either with or without an accommodation, he had no claim under the ADA. The court noted that hiring a nurse to give the immunizations for plaintiff, or requiring other pharmacists to handle them were not accommodations, but exemptions, which the ADA does not require.

Appellate Division Upholds City's Salt Labeling Rule

Nat'l Rest. Ass'n v. N.Y. City Dep't of Health & Mental Hygiene, 2017 WL 549039 (1st Dep't 2017). Petitioner, the National Restaurant Association (the "Association"), brought an Article 78 proceeding challenging the New York City Board of Health's adoption of a rule that required chain restaurants with 15 or more locations to post a salt shaker symbol on their menu next to any food item that contains 2,300 mg or more of sodium with a notation that the sodium content of

such item is higher than the daily recommended limit, and that a high sodium intake can lead to increased blood pressure and risk of heart disease and stroke. The Association argued that the Rule violates the separation of powers doctrine, is arbitrary and capricious, violates members' First Amendment Rights, and is preempted by federal law.

The Appellate Division held that the Board did not overstep its boundaries in adopting the Rule. To determine whether the Board crossed the line between administrative rulemaking and legislative policy-making, the Court analyzed the four factors set forth in *Boreali v. Axelrod*, 71 N.Y.2d 1 (1987) which, taken together, may indicate that an agency has usurped legislative authority. Those factors include: (i) whether the agency engaged in impermissible policy-making by making "value judgments entail[ing] difficult and complex choices between broad policy goals to resolve social problems"; (ii) whether the agency adopted the regulation without the benefit of legislative guidance on a "clean slate"; (iii) whether the agency acted in an area of legislative debate and inaction; and (iv) whether the agency relied on its special expertise in developing the regulation.

Regarding the first factor, the Court held that the Rule does not attempt to solve a social problem by choosing between competing ends but rather attempts to give consumers information that will make them better able to make their own nutritional decisions. Noting that the Rule does not restrict or even regulate what chain restaurants may offer for sale, the Court held that the adoption of the Rule does not require the Board to make "value judgments" "entail[ing] difficult and complex choices between broad policy goals." The Court also held that the fact that the Rule is applied to some but not all restaurants does not mean that the Board engaged in legislative policymaking since the determination to apply the Rule to national fast food chain restaurants is grounded in promoting public health and is supported by data demonstrating that fast food restaurants sell foods with high amounts of sodium. Further, the Rule's provision that only national chain restaurants that offer "substantially the same menu items" at all franchises are required to comply makes it possible to effectively administer the Rule. Finally, the Court rejected the Association's argument that research recommending a daily sodium limit of 2300 mg is controversial. Finding that leading experts in the field support the data behind the Rule, the Court rejected the Association's contention that the Rule does not advance the social benefit asserted.

Turning to the second factor, the Court noted that the legislature has given the Board wide authority to regulate restaurants to control chronic diseases and exercise control over

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conditions affecting public health. This broad authority to adopt rules to accomplish these goals is evident in the Department's adoption of prior rules, including restricting the use of artificial trans fats, and mandating that chain restaurants post the calorie contents of menu items. The Court thus concluded that the Board was not writing on a clean slate given that it has always regulated restaurants as necessary to promote public health.

As for the final two factors, the Court held that the Association failed to show that sodium warning labels were ever the subject of vigorous debate in the legislature, and that the Board relied on its expertise in weighing the scientific evidence concerning the risks associated with excess sodium consumption. Based on the foregoing, the Court concluded that consideration of the *Boreali* factors indicates that the Board did not exceed its authority in adopting the Rule.

Turning to the Association's remaining arguments, the Court held that the trial court correctly found that the Rule does not violate the First Amendment. As the Court explained, to the extent the warning indicates that consumption of sodium in excess of the daily recommended limit may increase medical risks, scientific evidence demonstrates such information is factual, accurate and uncontroversial. In addition, the Court held that the Rule has a rational basis and is not arbitrary and capricious given that the reason the Rule was limited to only large fast food chain restaurants was based on health considerations and for purposes of making the Rule possible to comply with and administer.

Finally, the Court rejected the Association's argument that the federal Nutrition Labeling and Education Act (NLEA) preempts the Rule. As the Court explained, NLEA expressly provides that its preemption clause "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." Since the Rule constitutes a warning, it is expressly exempted under the statute from preemption.

Appellate Division Upholds New York City Ordinance Imposing the Same Restrictions on Electronic Cigarettes as on the Use of Conventional Cigarettes

NYC C.L.A.S.H. v. City of N.Y., 147 A.D.3d 97, 45 N.Y.S.2d 22 (1st Dep't 2017). Plaintiffs advocacy organization and an individual sought a declaration that a New York City ordinance, Local Law 152, which imposed the same restrictions on the use of electronic cigarettes as on the use of conventional cigarettes, was unconstitutional for violating the single subject rule of the New York Constitution, state law, and city charter. The trial court upheld that law. The First Department affirmed.

Chapter 5 of the Administrative Code Title 17 (§§ 17-501-17-514) regulates smoking of tobacco cigarettes in New York City's public places. The law was first enacted in 1988 and has been regularly amended to strengthen the restrictions. Local Law 152 further amended Chapter 5 of Administrative Code Title 17, similarly regulating electronic cigarettes.

Plaintiffs contended that the amendment violated the "one-subject rule" established by New York Constitution, Article III, § 15, Municipal Home Rule Law § 20(3), and New York City Charter § 32. The New York Constitution's one-subject rule prohibits legislative "logrolling," which is the "uniting of various objects having no necessary or natural connection with each other, in one bill, for the purpose of combining various pecuniary interests in support of the whole, which could not be combined in favor of either by itself." The rule was created in 1846 as a result of Aaron Burr persuading the New York Legislature to grant him a charter for a water company; hidden among the charter's provisions was a clause enabling him to establish a bank. The court held that State Constitution rule does not apply to city law, only to bills passed by the State Legislature.

Nevertheless, the court noted that there are parallel statutory provisions that govern local laws, which are contained in the New York City Charter and the Municipal Home Rules Law. Municipal Home Rule Law § 20(3) states that "[e]very such local law shall embrace only one subject, the title shall briefly refer to the subject matter," and Section 32 of the New York City Charter provides that "[e]very local law shall embrace only one subject. The title shall briefly refer to the subject-matter."

The court ruled that Local Law 152 did not run afoul of these versions of the one-subject rule because the amendment had a single purpose, which was proclaimed in its title, to add electronic cigarettes to existing smoking legislation. Accordingly, the court upheld the ordinance.

Second Circuit Finds That Pharmaceutical Company Could Have Violated the Telephone Consumer Protection Act by Faxing Unsolicited Invitation to Free Medical Event

Physicians Healthsource, Inc. v. Boehringer Ingelheim Pharms., Inc., 847 F.3d 92 (2d Cir. 2017). Plaintiff-Appellant is a medical practice that received an unsolicited fax from Boehringer Ingelheim, a pharmaceutical company, inviting one of its physicians to a free "dinner meeting," including a discussion of female sexual dysfunction and hypoactive sexual desire disorder ("HSDD"). At that time, Boehringer had submitted an application to the Food and Drug Administration (the "FDA") for approval of a drug intended to treat HSDD. On March 30, 2012, Plaintiff-Appellant filed a putative class action against Boehringer, alleging that it violated the Telephone Consumer Protection Act of 1991, as amended by the Junk Fax Protection Act of 2005, 47 U.S.C. § 227 (the "TCPA").

The TCPA declares it unlawful for any person within the United

States to send a fax that is an "unsolicited advertisement" without complying with certain op-out notice requirements. An "unsolicited advertisement" is defined, under the Act, as "any material advertising the commercial availability or quality of any property, goods, or services which is transmitted to any person without that person's prior express invitation or permission, in writing or otherwise." In 2006, the Federal Communications Commission (the "FCC") promulgated a regulation stating, in sum and substance, that a facsimile message promoting free goods or services qualifies as an unsolicited advertisement under the TCPA, as free seminars and publications often serve as a pretext to advertise commercial products and services.

Boehringer moved to dismiss the complaint, arguing that its fax was not an unsolicited advertisement under the terms of the TCPA. Specifically, Boehringer claimed that it was prohibited from promoting its HSDD drug at the dinner meeting, as the drug had not yet received FDA approval. Reading the 2006 FCC regulation to require proof that the unsolicited fax have a commercial pretext in order to constitute an advertisement, the district court granted Boehringer's motion and dismissed the action. The district court found that nothing in the fax indicated that the dinner meeting was a pretext to advertise any Boehringer product or service, and that the awareness that the dinner meeting would raise for HSDD and the demand for Boehringer's new drug was merely a "hypothetical future economic benefit" that did not "transform the [f]ax into an advertisement."

The Second Circuit vacated the district court's judgment, holding that, at the pleading stage, it is sufficient for the plaintiff asserting a TCPA claim to allege that the defendant sent it an unsolicited fax promoting a free seminar on a topic related to the defendant's products or services. The court endorsed the district court's determination that under the 2006 FCC regulation, the plaintiff must ultimately demonstrate a commercial pretext for the free seminar. However, the court asserted that it would impede the remedial purpose of the TCPA to require the plaintiff to provide specific facts regarding the products or services advertised at the seminar, particularly where the plaintiff did not even attend the seminar.

Applying this reasoning, the Second Circuit held that Plaintiff-Appellant stated a claim under the TCPA. Following discovery, Boehringer would be able to present evidence demonstrating that it did not advertise its products or services at the meeting. Although the court found it relevant that Boehringer was prohibited from promoting its new HSDD drug due to the pending application for FDA approval, it held that this restriction was not dispositive. The court noted that the drug was intended to treat the very medical condition that was to be discussed at the meeting, and that the FDA regulations did not necessarily prohibit Boehringer from mentioning that the drug would possibly be available in the future. The court also stated that it is possible that Boehringer used the seminar to advertise its other drugs or services. In a concurring opinion, Judge Leval interpreted the 2006 FCC regulation as deeming the fax in this case a per se violation, and plaintiff need not prove it was a pretext for or prelude to commercial promotion.

Appellate Division Holds That Allegedly Defamatory Statements Made by Hospital Administrators to FDA Investigator Are Protected by Absolute Privilege

Stega v. New York Downtown Hospital, 44 N.Y.S.3d 417 (1st Dep't 2017). Plaintiff was employed as a research scientist and chair of the Hospital's Institutional Review Board (IRB), which is responsible for reviewing, approving and overseeing biomedical research. In 2011, Luminant BioSciences, LLC, retained a physician, Dr. Leonard Farber, to create a research protocol for a clinical trial for a drug to be used for treatment of metastatic cancer. When Dr. Farber was unable to write the protocol, he engaged Plaintiff to do so, for which Luminant paid her $50,000. Shortly following approval of the study by the Hospital's IRB, Dr. Farber asked Plaintiff to take over the study due to lack of funding, and also asked for the money Plaintiff had received from Luminant. When Plaintiff declined, Dr. Farber resigned from the study. Plaintiff asked the Hospital to treat the study patients, whose care she oversaw. While it was considering taking over the Luminant study, the Hospital determined that Plaintiff had a conflict of interest arising from her role as chair of the IRB when the IRB assessed and approved the study, and that the money she was paid by Luminant belonged to the Hospital.

As a result, the Hospital terminated Plaintiff's employment. Plaintiff then filed a complaint with the FDA, expressing concern that patients in the study would not be properly supervised by the Hospital. In response, the FDA began an investigation, which included the FDA investigator meeting with the Hospital's Chief Medical Officer. Plaintiff alleged that the CMO told the investigator Plaintiff channeled funds from a study sponsor to her own research group, that she had indicated she could use her position on the IRB to get a patient accepted into the study, and that all approvals made while she was chair of the IRB were "tainted."

Denying Appellant's motion to dismiss the defamation claim, the Supreme Court held that the CMO's alleged statements were protected only by the "common interest" qualified privilege rather than an absolute privilege, because the FDA investigation lacked the indicia of a quasi-judicial proceeding. The Supreme Court held that, because a claim of qualified privilege is to be raised as an affirmative defense, it was prema-

ture to consider the issue on a dismissal motion.

The Appellate Division held that the complained-of statements were made in a quasi-judicial proceeding, rendering them subject to an absolute privilege, because the FDA is a quasi-judicial governmental entity with authority to enforce legal requirements. The court held that the FDA is an administrative agency responsible for ensuring that IRBs handle new drug trials properly, and that in connection with this role, 21 CFR Part 56 provides for proceedings where an investigator observes noncompliance with the law. Noting that the federal regulatory scheme allows for an adversarial hearing as well as court review of any final administrative action by the FDA Commissioner, the court held that all procedures created by the regulation of IRBs, including preliminary investigations, qualify as quasi-judicial.

The court noted that several New York State courts have applied an absolute privilege in the administrative context due to the expanding role of administrative law in rulemaking and adjudicative functions. The court noted that absolute privilege extends to complaint letters to a bar association's grievance committee, as well as to statements to administrative agencies even if the statements do not even result in an investigation or adversarial hearing.

In emphasizing that any and all statements to an FDA investigator are absolutely privileged, the Appellate Division held that it is irrelevant who made the complaint leading to the investigation, and also that it is immaterial that Plaintiff herself would not be the subject of any related FDA hearing.

The court also noted that there is a strong public interest in ensuring that individuals with information regarding research protocols for newly developed drugs are encouraged to speak fully and candidly, without the need for self-censorship.

Appellate Division Upholds Agency's Determination to Allow a Community Residential Facility in the Town of Eden

Town of Eden v. Delaney, 144 A.D.3d 1688, 41 N.Y.S.3d 820 (4th Dep't 2016). The New York State Office for People with Developmental Disabilities ("OPDD") granted an application to allow the establishment of a six-bed community residential facility for the developmentally disabled within the Town of Eden. The town brought a CPLR Article 78 proceeding in the Supreme Court, Erie County, to challenge the determination. Supreme Court transferred the case to the Appellate Division, Fourth Department.

The Appellate Division confirmed OPDD's determination. The court rejected the Town's contention that OPDD's notice was improper because it listed facilities determined to be not sufficiently similar to warrant consideration for the siting of a community residential facility. Citing Mental Hygiene Law § 41.34(c)(1)(C);(5), the court held that OPDD's notice was neither deficient in content or prejudicial merely because it listed that data.

The court also rejected the town's argument that OPDD violated Mental Hygiene Law § 41.34(a)(1) by not taking into account other state-licensed facilities that already existed in the town. The court explained that under Mental Hygiene Law § 41.34, an existing facility can only be considered during the siting process if it is similar to the proposed new facility, and a facility will only be similar if it is a community residential facility for the disabled. The court noted the facilities identified by the town—a senior assisted living residence, at least one nursing home, a drug treatment facility, and a day rehabilitation center—could not have been considered similar because they were not community residential facilities for the disabled.

The court further concluded that substantial evidence supported OPDD's determination that, under Mental Hygiene Law § 41.34(c)(5), the establishment of the proposed new community residential facility for the disabled would not result in a concentration of similar state-licensed facilities so as to substantially alter the nature and character of the area in the Town of Eden.

Bronx Supreme Court Holds That Hospital's Incident Report of a Patient's Assault of an Employee Is Exempt From Disclosure

Phillips v. City of N.Y., 54 Misc. 3d 294, 40 N.Y.S.3d 751 (N.Y. Sup. Ct. 2016). Plaintiff, a special education teacher, brought an action against the City of New York seeking damages for injuries that she allegedly sustained while working at Bronx Lebanon Hospital Center (the "Hospital"), in a unit where students with special needs attend classes.

During discovery, Plaintiff sought disclosure of the non-party Hospital's incident report and moved to compel the Hospital to comply with a subpoena *duces tecum*. The Court issued an order directing the Hospital to produce documents responsive to the subpoena for in camera inspection. In response, the Hospital produced an Office of Mental Health Incident Reporting Form (the "Incident Report") along with a privilege log. The Hospital asserted that the Incident Report was privileged and not subject to disclosure under Mental Hygiene Law § 29.29, New York Education Law § 6527, and Public Health Law § 2805-m. The Hospital also submitted an unredacted copy of the Incident Report for *in camera* inspection.

In opposition, Plaintiff asserted that the Incident Report was not privileged, or at least exempted from any privilege, because the Hospital failed to meet its burden to establish that the Incident Report was prepared in accordance with the procedures set forth in New York Education Law § 6527(3) and Public Health Law § 2805-l, and because the Incident Re-

port contained statements made by the Plaintiff.

The court rejected Plaintiff's arguments in their entirety and held that New York Education Law § 6527(3) and Mental Hygiene Law § 29.29, read together, automatically exempt from disclosure incident reports generated in response to "allegations of assault by a patient against an employee." In so holding, the court relied upon a 1991 Court of Appeals decision that found that the language in New York Education Law § 6527(3) is unequivocal and does not require that the party seeking to invoke the privilege meet a particular burden in order for the privilege to apply. *See Katherine F. ex rel. Perez v. State*, 94 N.Y.2d 200, 723 N.E.2d 1016 (1999). The court further held that Plaintiff was not entitled to the Incident Report as a party to the litigation because only statements made in a meeting at which incident reporting function occurs were exempt from the privilege.

Third Department Upholds Revocation of Physician's License to Practice Medicine Based on Intentional Misrepresentations of a Misdemeanor Crime

Kulik v. Zucker, 144 A.D.3d 1217, 40 N.Y.S.3d 658 (3d Dep't 2016). Petitioner, a physician licensed to practice medicine in New York, filed an Article 78 proceeding seeking review of a determination of the Hearing Committee of the State Board for Professional Medical Conduct which revoked Petitioner's license to practice medicine in New York.

In 2009, the Bureau of Professional Medical Conduct charged Petitioner with three specifications of professional misconduct for committing negligence on more than one occasion, ordering excessive tests, and failing to maintain records. In satisfaction of these charges, Petitioner entered into a consent agreement in which he agreed to, among other things, a censure, a reprimand, and a three-year period of probation. Shortly before the consent agreement became effective, Petitioner pleaded guilty to driving while impaired by drugs, which ultimately gave rise to 14 additional specifications of professional misconduct, including, practicing medicine fraudulently, filing a false report, committing an act constituting a crime in New York, and violating a term of probation.

Following a hearing before the Hearing Committee of the State Board for Professional Medical Conduct, all 14 specifications of professional misconduct were sustained. In so holding, the Hearing Committee found that Petitioner intentionally misrepresented or concealed on a registration renewal the fact that he had criminal charges pending against him. The Hearing Committee also found that Petitioner intentionally misrepresented or concealed on a renewal form and two separate hospital reappointments forms his subsequent guilt. Petitioner admitted to those misrepresentations, but maintained that they were not intentional because he thought his driving while impaired offense was a minor traffic infraction, not a misdemeanor crime. At the hearing, six witnesses testified to Petitioner's honesty and moral fitness to practice medicine. The Hearing Committee revoked Petitioner's license, noting that Petitioner lacked remorse and disregarded the seriousness of his actions.

Petitioner thereafter commenced an Article 78 proceeding, contending that license revocation was excessive and harsh in light of the evidence of his good character and because his conduct did not involve patient care. The court found that revocation was proper because it was Petitioner's second time before the State Board for Professional Medical Conduct, he concealed the fact that he pled guilty during the negotiation of his consent agreement, and made numerous misrepresentations during his three-year probation period.

The court held that the penalty imposed by the Hearing Committee would not be disturbed because it was not so incommensurate with the offense as to shock one's sense of fairness. The court also noted that the fact that patient care was not implicated does not preclude revocation of Petitioner's license, and that evidence of fraudulent conduct, standing alone, was sufficient to uphold the penalty of revocation.

Legislative Update
The Resilience of Antiquated New York Health Law Principles in a Transformed Health Care Environment

By James W. Lytle

Despite the massive transformation of the health care system over the past several decades and the promise of even more substantial changes to come, it is remarkable that some arguably outdated legal principles that underlie the health care system in New York have been so impervious to change.

The powerful implications of the revolution in health care information technology, the massive growth of health care systems, the explosion in multi-specialty group mega-practices, unprecedented consolidation among health plans, the advent of retail health care clinics and the implications of federal health reform (and the likely consequences of its potentially imminent undoing) have somehow left antiquated health law conventions largely unaffected. While New York State is widely viewed as a progressive state, it is remarkable that legal principles that seem tied to an earlier health law era remain unchanged and that legislative efforts to reform those arguably anachronistic legal rubrics have been notably and consistently unsuccessful.

Consider these three New York health law principles that have bedeviled health lawyers for generations and that are so constraining and immutable as to be worthy of comparison to the Ten Commandments:

- the New York State ban on corporate practice of a profession;
- the fee-splitting prohibition; and
- the prohibition on professional practices co-owned by physicians and other licensed professionals.

In all three cases, the New York State Legislature has considered reforming, updating or otherwise modifying these longstanding legal rules but, in all three cases, these legislative efforts have been unavailing.

Corporate practice: The novice health lawyer will search in vain for an explicit prohibition of the "corporate practice of medicine" or "corporate practice of a profession," a ban that does not exist quite so precisely in New York law. In a 1998 report on the subject, the State Education Department defined the ban as follows:

> Section 6512 of the Education Law stipulates that it is a felony for an unlicensed person to practice a licensed profession. Further, Section 6513 of the Education Law provides that the unauthorized use of a professional title is a crime. Given these provisions, it is clear that business corporations cannot hire a licensee to provide professional services because the law neither authorizes such action nor provides an exemption. This serves to protect the public from a business relationship that could place constraints upon professional judgment, unduly limit professional practice, invade the professional integrity of the professional, or permit the business corporation to make professional decisions.[1]

Although professionals may practice as individuals or in professional partnerships, professional corporations, professional limited liability partnerships, and professional limited liability companies, they may not be employed by business corporations or even not-for-profit organizations, absent some explicit statutory or regulatory exception permitting the practice. For example, physicians may be employed by a health maintenance organization[2] and by an independent practice association (IPA)[3] and eyeglasses and contact lenses "may be sold by any person, firm or corporation at retail,"[4] even though optometrists and opticians are otherwise subject to the same limitation on corporate professional practice. By court decision, medical school sponsored faculty practice plans, which employ physicians to provide professional services, have been determined to be outside of the corporate practice ban.[5]

Despite these exceptions and the increasing proliferation of professional services in commercial and corporate settings, the corporate practice ban remains alive and well. In June, 2015, the New York State Attorney General's office entered into an Assurance of Discontinuance with Aspen Dental Management, Inc., largely premised on a determination that the dental management company had effectively engaged in the non-licensed practice of dentistry and dental hygiene.[6]

The legislative consideration of the issue in recent years has focused on retail clinics. Even though pharmacies and other retail commercial enterprises have increasingly incorporated the delivery of health care services within their service portfolio, they have done so in New York through somewhat complicated relationships between lawful professional service corporations and their

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corporate sponsor and landlord.[7] Legislation to authorize and regulate retail clinics has been introduced in the New York since 2010, but has not been enacted.[8] Over the course of three consecutive years (2014-2016), Governor Andrew Cuomo proposed legislation as part of his Executive Budget that would allow for the licensing of "limited service clinics"[9]—essentially diagnostic and treatment centers operating in retail establishments—and that would have required them to maintain electronic health records, forward information regarding their service to a patient to the patient's primary care practitioner, maintain accreditation and limit their services to certain primary care interventions. The budget legislation was not, however, ultimately enacted as part of any of those prior budgets and the Governor did not advance a similar proposal in 2017.

Thus, even with a strong push from the Department of Health and the Administration to bring retail clinics into a more explicit regulatory framework and seven years of pending legislation to do likewise, retail clinics remain outside of formal recognition in New York law and must continue to conduct themselves in a manner that does not offend the New York ban on corporate practice.

Fee-splitting: Unlike the corporate practice ban, the prohibition on professional fee-splitting in New York is explicit: section 6509-A of the Education Law defines professional misconduct to include instances in which the professional has "directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for, or has directly requested, received or profited by means of a credit or other valuable consideration as a commission, discount or gratuity in connection with the furnishing of professional care, or service," subject to certain enumerated exceptions. Likewise, the rules of governing professional misconduct also prohibit:

> permitting any person to share in the fees for professional services, other than: a partner, employee, associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice the same profession, or a legally authorized trainee practicing under the supervision of a licensed practitioner. This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment or personnel services used by a professional licensee constitutes a percentage of, or is otherwise dependent upon, the income or receipts of the licensee from such practice, except as otherwise provided by law with respect to a facility licensed pursuant to Article 28 of the Public Health Law or Article 13 of the Mental Hygiene Law.[10]

New York's strict rules on fee-splitting have become somewhat of an outlier:[11] 17 states do not have laws or regulations prohibiting fee-splitting,[12] several states limit the prohibition to sharing fees among professionals (as opposed to arrangements that might involve outside entities, like professional management or billing companies)[13] and California and Illinois have amended their fee-splitting prohibitions to permit percentage-based arrangements between professionals and billing and professional management companies.[14] Nevertheless, even if the New York law is no longer in the mainstream, it is alive and well, as evidenced by the Aspen Dental Management matter referenced above (which focused on fee-splitting as well as corporate practice issues) and by a recent investigation by the Medicaid Fraud Control Unit on percentage billing arrangements with one or more billing companies.

Legislation has been introduced over the last several sessions that would allow licensed professionals to pay a fee to vendors of practice management, billing or health information technology services based on a percentage of fees billed or collected, a flat fee, or any other arrangement, provided that the licensed professionals (a) are responsible for the contents of claims submitted, (b) receive the third-party payments in their own name, and (3) do not receive referrals from the vendor.[15] Although the bill passed the Senate in 2016, it has not yet progressed in the State Assembly.

Multi-professional services corporations: New York has witnessed the growth of large multi-specialty practices, where a wide array of professionals are assembled to provide a continuum of services to prospective patients, spanning any number of professional categories. The days of small practices, managed by a handful of practitioners, all in the same professional license category, may soon be over, relegated to the Marcus Welby or Dr. Kildare era. While a wide variety of professions may be employed in a large physician-led group practice, New York law does not permit non-physician professionals to co-own these practices with their physician colleagues.

Under the relevant provisions of the Business Corporation Law, professional services corporations ("PCs") may only be established and owned by the same category of licensed professionals in New York: i.e., a medical P.C.may only be owned by physicians, a psychologists' P.C. may only be owned by psychologists, etc.[16] The authorization of Professional Limited Liability Companies permitted some inter-professional ownership of professional PLLCs—e.g, psychologists and social workers, chiropractors and physical therapists or optometrists and opticians might co-own their own PLLC—but even that statute precluded any professional practice organization that rendered medical services to be owned by anyone other than physicians.[17] As a result, non-physicians must content themselves with being employees in physician-led multi-professional practices and are precluded from owning a piece of the practice.

Legislation to address this issue has been advanced by various professions. A bill to permit chiropractors and physicians to form a limited liability company has been considered for several years, since its initial introduction in 2011,[18] and a similar bill that would permit optometrists and opticians to co-own practices with ophthalmologists was considered in 2015-16.[19] More recently, a group of professions have banded together to try to enact omnibus legislation that would authorize co-ownership of professional practices with physicians. The omnibus bill (Assembly Bill No. 1943 (People-Stokes)/Senate Bill No. 4125 (LaValle)) would permit chiropractors, pharmacists, midwives, podiatrists, optometrists, ophthalmic dispensers, psychologists, social workers, massage therapists, occupational therapists and nurse practitioners to establish practices with physicians.

As with reforms of these other arguably anachronistic New York rules, the effort to authorize co-ownership of practices with physicians by other licensed professionals has not yet been successful. One might imagine that a Legislature progressive enough to authorize marriage between consenting adults of the same sex would allow two consenting professionals from different professions to form a professional corporation, but no such luck.

Endnotes

1. *Corporate Practice of the Professions,* Office of the Professions, New York State Education Department, available at http://www.op.nysed.gov/corp/corppractice.htm.
2. Public Health Law, §4405(2).
3. 10 NYCRR 98-1.2(w).
4. Education Law, §§7106(2), 7126(1).
5. *Albany Medical College v. McShane*, 66 N.Y.2d 982 (1985).
6. For the terms of the Assurance of Discontinuance, go to https://ag.ny.gov/pdfs/ADMI_AOD.pdf
7. For a detailed discussion on the role of retail clinics in New York State, see J. Chang, S. Brundage, G. Burke, and D. Chokshi, *Convenient Care: Retail Clinics and Urgent Care Centers in New York,* United Hospital Fund, February, 2015.
8. See, e.g., Assembly Bill No. 958 (Paulin) introduced in 2017 session; no companion bill is currently before the State Senate, where a comparable bill has not been introduced since 2010.
9. See Part G, Assembly Bill No. 9007(2016).
10. 8 NYCRR §29.1(4).
11. This discussion draws substantially on an article by my colleagues, Mark Ustin and Carol Brass, *An Examination of Fee-Splitting Statutes in the Context of Value-Based Health-Care,* BNA's Medicare Report, 26 MCR 723, June 5, 2015, available at: http://www.jdsupra.com/legalnews/an-examination-of-fee-splitting-99175/).
12. There are no statutory or regulatory fee-splitting prohibitions in the following states: Alaska, Arkansas, Connecticut, Indiana, Iowa, Louisiana, Maine, Massachusetts, Mississippi, Missouri, New Hampshire, New Jersey, North Dakota, Oregon, Pennsylvania, South Carolina, and Wyoming.
13. Arizona, Delaware, Michigan, Minnesota, Nevada, Ohio, and Virginia have fee-splitting statutes which only prohibit fee-splitting among professionals.
14. See Cal. Bus. & Prof. Code § 650 and 225 Ill. Comp. Stat. 60/22.2(d).
15. Assembly Bill No. 193 (Buchwald)/Senate Bill No. 2247 (Hannon) in the 2017 legislative session.
16. See Business Corporation Law, § 1503(a).
17. See Limited Liability Company Law, § 1203(a).
18. Assembly Bill No 5807 (O'Donnell)/Senate Bill No. 4291 (Funke).
19. Assembly Bill No. 991(Cahill).

For Your Information

By Claudia O. Torrey

The following words by this author reflect a brief commentary regarding the "state of health" of the health law profession. As we move forward with the current White House Administration in the process of putting its "handprint" on American health care and health related issues, it is hoped that we as health law attorneys subscribe to a MORAL COMPASS irrespective of whether or not our client is an individual or corporation. For example:

> Assist corporations in setting a high bar for pollutants not degrading our air and water systems, in spite of regulations/statutes that may allow such;
>
> Speak up for people who may lose their health insurance through no fault of their own; and/or
>
> Speak out for older persons, disabled persons, and Medicare/Medicaid recipients, all of whom may find that they are at the end of a health care system that cares less for them, and more for politicians who benefit from being on a government health plan.

The moral compass mentioned above for health law attorneys should be viewed like the "first do no harm"[1] command for health care practitioners.

Taking the high road is not always easy, but it usually leads to success (not necessarily financial success). In the words of R. Buckminster Fuller: "If humanity does not opt for integrity we are through completely. It is absolutely touch and go. Each one of us could make the difference."

Endnote

1. Often attributed to the Greek Hippocratic Oath, which does not explicitly contain the phrase (See nlm.nih.gov, Greek Medicine, History of Medicine Division/National Library of Medicine/National Institutes of Health, 2002)(last updated February 7, 2012).

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In the New York State Agencies

By Francis J. Serbaroli

Perinatal Services

Notice of Adoption. The Department of Health amended section 405.21 of Title 10 NYCRR to update the Breastfeeding Mother's Bill of Rights to conform with recommended standards of care. Filing date: September 28, 2016. Effective date: January 1, 2017. *See* N.Y. Register October 19, 2016.

New York State Newborn Screening Panel

Notice of Adoption. The Department of Health amended section 69-1.2 of Title 10 NYCRR to add adrenoleukodystrophy (ALD) and Pompe disease to the list of diseases and conditions on the newborn screening panel. Filing date: September 28, 2016. Effective date: October 19, 2016. *See* N.Y. Register October 19, 2016.

Women Infants and Children (WIC) Program Vendor Applicant Enrollment Criteria

Notice of Expiration. The notice proposed on September 30, 2015 expired on September 29, 2016 and cannot be reconsidered unless the Department of Health publishes a new notice of proposed rulemaking. *See* N.Y. Register October 19, 2016.

Repeal Parts 309, 369, 829, 1000, 1034, 1050, 1070 and 1072 of Title 14 NYCRR

Notice of Withdrawal. The Office of Alcoholism and Substance Abuse Services withdrew from consideration a notice of proposed rulemaking published in the State Register on August 24, 2016 concerning the repeal of Parts 309, 369, 829, 1000, 1034, 1050, 1070 and 1072 of Title 14 NYCRR because of comments received. *See* N.Y. Register November 2, 2016.

Practice of Radiologic Technology

Notice of Adoption. The Department of Health amended Part 89 of Title 10 NYCRR to update regulations related to the practice of radiologic technology. Filing date: October 18, 2016. Effective date: November 2, 2016. *See* N.Y. Register November 2, 2016.

Neurodegenerative Specialty Rate

Notice of Adoption. The Department of Health amended Subpart 86-2 of Title 10 NYCRR to authorize Medicaid rate of payment for providing quality of care to the neurodegenerative population. Filing date: October 18, 2016. Effective date: November 2, 2016. *See* N.Y. Register November 2, 2016.

Specialized Programs for Residents with Neurodegenerative Diseases

Notice of Adoption. The Department of Health added section 415.41 to Title 10 NYCRR to establish nursing home specialty units for residents with Huntington's Disease (HD) and Amyotrophic Lateral Sclerosis (ALS). Filing date: October 18, 2016. Effective date: November 2, 2016. *See* N.Y. Register November 2, 2016.

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

Notice of Adoption. The Department of Financial Services amended Part 52 (Regulation 62) of 11 NYCRR to allow blanket accident insurance policy issued in accordance with GBL section 1015.11 to be excess to any plan. Filing date: November 1, 2016. Effective date: November 16, 2016. *See* N.Y. Register November 16, 2016.

Zika Action Plan; Performance Standards

Notice of Adoption. The Department of Health added section 40-2.24 to Title 10 NYCRR to require local health departments to develop a Zika Action Plan as a condition of State Aid. Filing date: November 8, 2016. Effective date: November 23, 2016. *See* N.Y. Register November 23, 2016.

Early Intervention Program

Notice of Adoption. The Department of Health amended Subpart 69-4 of Title 10 NYCRR to conform existing program regulations to federal regulations and state statute. Filing date: November 15, 2016. Effective date: November 30, 2016. *See* N.Y. Register November 30, 2016.

Medical Use of Marihuana

Notice of Adoption. The Department of Health amended section 1004.1(a)(2) of 10 NYCRR to authorize nurse practitioners to register with the Department in order to

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

issue certifications to patients with qualifying conditions. Filing date: November 15, 2016. Effective date: November 30, 2016. *See* N.Y. Register November 30, 2016.

Transgender-Related Care and Services

Notice of Adoption. The Department of Health amended section 505.2(1) of Title 18 NYCRR to amend provisions regarding Medicaid coverage of transition-related transgender care and services. Filing date: November 22, 2016. Effective date: December 7, 2016. *See* N.Y. Register December 7, 2016.

Agency Name Change Terminology Update

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposed a consensus rulemaking to amend Part 622 of Title 14 NYCRR to update the agency name in Title 14 NYCRR Part 622 regulations. *See* N.Y. Register December 7, 2016.

HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 63 of 10 NYCRR to simplify HIV testing consent and improve linkage to care. *See* N.Y. Register December 14, 2016.

Expansion of Minor Consent for HIV Treatment Access and Prevention

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 23.1 and 23.2 of Title 10 NYCRR to allow qualified clinicians to provide antiretrovirals for treatment and prophylaxis. *See* N.Y. Register December 14, 2016.

Lead Testing in School Drinking Water

Notice of Emergency Rulemaking. The Department of Health added Subpart 67-4 of Title 10 NYCRR to require lead testing in school drinking water. Filing date: December 5, 2016. Effective date: December 5, 2016. *See* N.Y. Register December 21, 2016.

Federal Conditions of Participation

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 405 of Title 10 NYCRR to reflect amendments consistent with updated Federal Conditions of Participation. *See* N.Y. Register December 21, 2016.

Medical Use of Marihuana – Chronic Pain

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 1004.1 and 1004.2 of Title 10 NYCRR to add any severe debilitating or life-threatening condition causing chronic pain. *See* N.Y. Register December 21, 2016.

Repeal Part 830 and Add New Part 830 Regarding Ancillary Services and Therapies

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse proposed repealing Part 830 and adding a new Part 830 to Title 14 NYCRR to repeal obsolete regulations and incorporate provisions into a new Part with additional provisions. *See* N.Y. Register December 28, 2016.

Repeal Parts 321 and 1055; Add New Part 813 Regarding Financing Capital Improvements

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse proposed repealing Parts 321 and 1055 and adding Part 813 to Title 14 NYCRR to repeal DSAS/DAAA regulations and consolidate provisions into a new Part 813. *See* N.Y. Register December 28, 2016.

Repeal Obsolete Rules: Outpatient Chemical Dependency Services for Youth Programs and Services

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse proposed a consensus rulemaking repealing Part 823 of Title 14 NYCRR to repeal obsolete rules of the Office. *See* N.Y. Register December 28, 2016.

Establishment and Operation of Market Stabilization Mechanisms for Certain Health Insurance Markets

Notice of Emergency Rulemaking. The Department of Financial Services amended Part 361 and added section 361.9 to Title 11 NYCRR to allow for the implementation of a market stabilization pool for the small group health insurance market. Filing date: December 7, 2016. Effective date: December 7, 2016. *See* N.Y. Register December 28, 2016.

Residential Health Care Facility Quality Pool

Notice of Emergency Rulemaking. The Department of Health added section 86-2.42 to Title 10 NYCRR to reward NYS facilities with the highest quality outcomes as determined by methodology developed by regulation. Filing date: December 19, 2016. Effective date: December 19, 2016. *See* N.Y. Register January 4, 2017.

Expanded Syringe Access Program

Notice of Adoption. The Department of Health amended section 80.137 of 10 NYCRR to eliminate the word "demonstration." Filing date: December 19, 2016. Effective date: January 4, 2017. *See* N.Y. Register January 4, 2017.

Hearing Procedures Update

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposed a consensus rulemaking to amend section

602.5 of Title 14 NYCRR to correct a grammatical error. *See* N.Y. Register February 1, 2017.

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

Notice of Proposed Rulemaking. The Department of Financial Services proposed adding sections 52.1(p), 52.2(y), (z), (aa) and 52.16(o) to Title 11 NYCRR to ensure that medically necessary abortion coverage is maintained for all insureds. *See* N.Y. Register February 8, 2017.

Agency Name Change Terminology Update

Notice of Adoption. The Department of Health amended Part 622 of Title 14 NYCRR to update the agency name. Filing date: January 24, 2017. Effective date: February 8, 2017. *See* N.Y. Register February 8, 2017.

Adult Day Health Care Services for Registrants with AIDS

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 86, 425 and 759 of Title 10 NYCRR to provide programs with the ability to register and service other high-need populations. *See* N.Y. Register February 15, 2017.

Public Water Systems

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 5-1 of Title 10 NYCRR to incorporate federal rules and revisions to the Public Health Law. *See* N.Y. Register February 15, 2017.

Certification of Facilities and Home- and Community-Based Services (HCBS)

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposed adding Part 619 and amending Parts 633, 635, 671, 679, 681, 686 and 690 of Title 14 NYCRR to update, reorganize, and relocate existing requirements for certification of programs and services in the Office's system. *See* N.Y. Register February 22, 2017.

Non-Prescription Emergency Contraceptive Drugs

Notice of Adoption. The Department of Health amended section 505.3 of Title 18 NYCRR to allow pharmacies to dispense non-prescription emergency contraceptive drugs for Medicaid female recipients without a written order. Filing date: February 20, 2017. Effective date: March 1, 2017. *See* N.Y. Register March 1, 2017.

Residential Health Care Facility Pool

Notice of Emergency Rulemaking. The Department of Health added section 86-2.42 to Title 10 NYCRR to reward NYS facilities with the highest quality outcomes as determined by methodology developed by regulation. Filing date: February 17, 2017. Effective date: February 17, 2017. *See* N.Y. Register March 8, 2017.

Compounded Trend to Cost of Living Adjustments (COLAs) for Direct Care Workers

Notice of Adoption. The Department of Health amended Subpart 86-10 of Title 10 NYCRR to update the methodology to reflect a compounded cost of living adjustment and to remove a superfluous component. Filing date: February 16, 2017. Effective date: March 8, 2017. *See* N.Y. Register March 8, 2017.

Direct Clinical Services—Supervised Individual Residential Alternatives (IRAs), Community Residences (CRs) and Day Habilitation

Notice of Adoption. The Department of Health proposed amending section 86-10.5 of 10 NYCRR to exclude direct clinical services from the reimbursement for Supervised IRAs, CRs and Day Habilitation. *See* N.Y. Register March 15, 2017.

Medical Use of Marihuana—Physician Assistants

Notice of Adoption. The Department of Health proposed amending sections 94.2(e)(6) and 1004.1(a)(2) of Title 10 NYCRR to authorize physician assistants to register with the Department in order to issue certifications to patients with qualifying conditions. *See* N.Y. Register March 15, 2017.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions[1]

Compiled by Margaret Surowka Rossi and Caitlin J. Monjeau

Renaissance Rehabilitation and Nursing Care Center (DOH administrative hearing decision dated September 26, 2016, Jude Brearton Mulvey, Administrative Law Judge). The ALJ rejected a skilled nursing facility's argument that it should not have to repay NAMI payments due to the lag time between services and the receipt of the budget letter. This was an audit of Appellant's long-term care services for residents of its 120-bed nursing facility for the period October 1, 2009 through November 30, 2011. At issue was OMIG's position that 12 claims had not been reduced in part or full by the Net Available Monthly Income ("NAMI"—the amount that a Medicaid recipient must contribute toward his/her care), resulting in an overpayment of $6,637.79. The facility disputed this, asserting that "the State cannot expect a provider to collect from a resident or from his/her family NAMI obligations that the provider was not even made aware of until months or even years after the local social services district got around to notifying the facility." OMIG introduced an October 26, 2001 "Dear Administrator" letter instructing providers not to bill Medicaid until they receive a budget letter from the local social services district indicating the NAMI amount. In this case, the NAMI determination ("budget letter") was received by the facility several months after the resident was admitted. The facility did not dispute the NAMI amounts at issue or the accuracy of the overpayment calculation. The issue is solely whether the facility is "absolved of a duty to reimburse the Medicaid program for this amount due to the timing of the receipt of the budget letter." In this regard, the facility introduced no policies or regulations that would absolve it of its responsibility. The ALJ reiterated that the Dear Administrator letter was very specific. Moreover, OMIG's auditor testified that there were other billing options available including continuing to bill the resident as a private pay resident or classifying the resident as "Medicaid-pending" and collecting an estimated NAMI amount. The facility did not delineate any efforts to ascertain the appropriate NAMI prior to the submission of the claims and the evidence indicated that the facility was inconsistent and in several instances it could prospectively calculate the NAMI before receipt of the actual budget letter. As such, the ALJ found that the facility failed to meet its burden and upheld the overpayment determination.

Reliance Ambulette, Inc. (DOH administrative hearing decision dated August 23, 2016, Denise Lepicier, Administrative Law Judge). The ALJ rejected a transportation provider's arguments of retroactivity. This transportation provider audit was conducted by New York City Human Resources Administration ("HRA"), under the oversight of OMIG, seeking recoupment of $2,659,293.15. The audit consisted of 200 claims paid in the period between January 1, 2005 and December 31, 2006 for Medicaid transportation services. The majority of the claims at issue were disallowed due to the failure of the drivers to have NYC Taxi and Limousine ("TLC") licenses as the provider claimed it was unaware that TLC licenses were required prior to 2008. There were additional disallowed claims, such as those for inaccurate procedure code, inaccurate driver's license number or name and failure to have 19A certification, where the provider contested the appropriateness of extrapolation. The provider first claimed that as to the TLC licenses, there was no notice of such requirement. Specifically, it noted that the regulation cited in the audit reports was not in effect and therefore OMIG was retroactively applying law and guidance which would be improper (citing *In the Matter of Christian Ambulette, Inc.* (10/09/2013)). The ALJ concurred but noted that the question is what the law, regulation and guidance was at the time the claims were submitted. The regulation in effect at the time, 18 NYCRR § 505(e), stated that "Ambulette services and their drivers must comply with all requirements of the Department of Transportation and the Department of Motor Vehicles . . . . [and] ambulette services operating in New York City must be

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licensed by the New York City Taxi and Limousine Commission." The provider argued that the regulation, unlike the subsequent guidance, said nothing about the drivers and that since the corporation was TLC licensed, it was in compliance. OMIG argued that the regulation includes driver requirements. The ALJ agreed, pointing to the Rules of the City of New York which specifically provided that a driver of a paratransit vehicle must be licensed and stating: "Indeed, to accept the Appellant's argument that only the base (company) needed to be licensed would be to accept the premise that a licensed ambulette company can ignore the very rules governing its operation under its TLC license, an absurd result." Provider then objected, saying that it was unable to determine the specific reason behind the disallowance of several claims. The ALJ thoroughly reviewed the procedural background and noted that the Appellant's responses to the Exit Conference report and the DAR and Revised DAR indicated that it fully understood the problems identified by the auditors. The ALJ rejected any suggestion that the auditors should have told the provider what documentation it would accept as proof. The Appellant provider then argued that the length of time between the date of service and the Revised DAR, over eight years, prejudiced its right to defend itself as witnesses and documents were no longer available. Since the notice of the audit itself was within the six-year statute of limitations, this claim was also rejected. The ALJ also rejected the argument that "minor documentation issues, which are often matters of subjective interpretation" were never intended to "deny payment for services actually rendered," stating that "providers enter an agreement with the Medicaid program to provide services in accord with the rules. If providers do not meet their obligations, they are in breach of that agreement. No provider is forced to participate in the Medicaid program, but if the provider becomes a participant, that provider must strictly adhere to program requirements." The ALJ also rejected the final objection raised in the Appellant's response to the Revised DAR that extrapolation is inappropriate, as no expert was produced challenging the OMIG affidavits certifying the validity of the sampling and extrapolation methodology. At the hearing and in its post-hearing briefs, the Appellant also raised new issues including an objection to the failure of Medicaid to institute a "computerized program edit" to reject claims with inaccurate or incomplete information. These new issues were all rejected because they were not raised in the response to the DAR or the revised DAR. As a result, the ALJ affirmed OMIG's determination to recover Medicaid overpayments in the amount of $2,659,293.15.

IMI Transport Inc. (DOH Administrative Hearing decision dated July 21, 2016, Kimberly A. O'Brien, ALJ). The ALJ rejected a proposed recovery of $691,221, finding instead that the OMIG was entitled to recover only $436.50 from an ambulette provider. The OMIG audited a sample of 150 claims for transportation services rendered between 2006 and 2009, and disallowed payment for 118 of those claims based upon missing information on the submitted claims (114 claims), missing or incomplete supporting documentation (2 claims), and a lack of 19-A certification for the driver (2 claims). The provider supplied contemporaneous documentation substantiating 146 of the 150 sample claims, but the OMIG issued a final audit report seeking recovery for 118 of the 150 claims anyway. At the exit conference, a private contractor retained by the OMIG created a list of vehicle assignments concerning 114 sample claims that allegedly included inaccurate vehicle plate numbers or driver's license numbers, and apparently used this list to disallow payment for these claims. The ALJ held that this list was irrelevant to the audit, rejecting the OMIG's argument that this list was "all the appellant had" to substantiate its claims. The ALJ found that "[t]he OMIG, simply, and inexplicably, ignored the documentation submitted by the Appellant in response to the draft audit report," and characterized the OMIG's decision as "nonsense and confusion." Moreover, the OMIG did not indicate in its draft or final audit reports that this list was the basis for its disallowances. The ALJ found that the provider showed that each of the denied claims were contemporaneously documented and were properly paid by the Medicaid program. With respect to a license plate number that was missing one digit, but that was otherwise recognizable as one of the provider's vehicles, the ALJ rejected the OMIG's determination that claims associated with that vehicle should be recovered. The ALJ did find that the provider could not document the first leg of a round-trip in two cases, and directed overpayment of $236.50 on those claims. For the two claims for which a driver was not 19-A certified, the ALJ found recovery of $200 was proper. The ALJ rejected the remaining 114 claims and directed the provider to repay a total of $436.50.

Allan Roffe, D.D.S. (DOH administrative hearing decision dated June 16, 2016, James F. Horan, Administrative Law Judge). The ALJ rejected OMIG's determination to recoup an incentive payment. This was a review of an OMIG determination to seek recoupment of $21,250.00 in Medicaid incentive funds to adopt or upgrade an electronic health record (EHR) system. OMIG sought recoupment in that amount on the grounds that the dentist falsely attested to adopting to EHR in 2011 when he did not actually adopt the EHR until 2012. The ALJ found that the evidence did not support OMIG's position. OMIG argued that the Appellant's Attestation was for the year 2011, as the grace period for 2011 was extended until April 20, 2012 and the Attestation was signed on April 23, 2012. The ALJ determined that the Appellant was unaware that he was submitting an Attestation for the 2011 year in the grace period. The Attestation did not include any language or representation that the certified EHR system had been adopted in 2011. As such, Judge Horan found there was no

ground for recoupment and the Final Audit Report Determination was overturned.

Rite Aid of New York Store #1852 (DOH Administrative Hearing decision dated May 27, 2016, James F. Horan, Administrative Law Judge). The ALJ rejected a res judicata argument where a pharmacy had already been penalized by the New York State Board of Pharmacy for the same self-disclosed issue. The pharmacy had reported to the Board of Pharmacy that it inadvertently destroyed original prescriptions while attempting to exterminate rodents in the store, and in 2006, the pharmacy entered a consent decree to resolve the issue, which included payment of a $10,000 fine and two years' probation. In 2009, the OMIG moved to recover more than $4.6 million in overpayments stemming from the absence of prescriptions or fiscal orders for 63,664 Medicaid claims based upon the missing prescription documents. The OMIG later issued an amended notice of proposed agency action that added its intention to censure and reprimand the pharmacy and an alleged HIPAA violation, although it withdrew both allegations at hearing. OMIG also withdrew its proposed $4.3 million recoupment request and instead sought $246,267, which reflected the $4.50 dispensing fee for 54,762 prescriptions during the audit period. The pharmacy argued in response, among other things, that the 2006 Board of Pharmacy consent decree barred the OMIG from retrying the matter under the doctrine of res judicata. Relying on *Koch v. Sheehan*, 21 N.Y.3d 697 (2013), the ALJ held that the Board of Pharmacy's consent decree did not trigger res judicata and therefore the OMIG was free to attempt to recover Medicaid payments The ALJ permitted the OMIG to recoup the $4 average dispensing fee for each of 54,726 destroyed prescriptions, for a total of $218,904.

ClearView Center, Inc. (DOH Administrative Hearing decision (not dated) 2016, Dawn MacKillop-Soller, ALJ). The ALJ rejected due process and timeliness arguments and upheld OMIG's proposed recovery of $109,880.46 for Level I COPS and CSP overpayments made between 2003 and 2005 to an outpatient behavioral health provider. These supplemental payments, which have since been discontinued or rolled into the revised payment scheme for clinics, were subject to an annual threshold cap. The Office of Mental Health was responsible for recovering any payments made in excess of the cap. In 2009, the OMIG notified the provider of its intention to recover $356,229.68, later revised to $109.880.46. The provider argued that the OMIG did not have the authority to recover COPS and CSP overpayments, the OMIG and OMH did not adhere to timing parameters for conducting Medicaid audits, and the recovery action was delayed and should be barred. The ALJ rejected all three arguments, finding that the OMH could cooperate with OMIG to recover Medicaid funding, even if the cooperative arrangement is not committed to writing. With respect to notice requirements, the ALJ found that these were only applicable to on-site audits, not desk audits as the audit was here. Finally, relying on *Blossom View Nursing Home v. Novello*, 4 N.Y.3d 581 (2005), the ALJ held that the OMIG timely commenced the recovery action within six years of the alleged overpayments, and that the provider's laches defense could not be used against the state in a case like this one.

New York State Attorney General and New York State Comptroller's Office Press Releases

Compiled by Caitlin J. Monjeau and Bridget Steele

Medical Supply Company Owner Arrested for Alleged Medicaid Fraud—February 25, 2017—The owner of a Valley Stream medical supply company was arrested for allegedly billing for over $1.5 million in improper Medicaid payments. The provider allegedly used a false Social Security Company to register with the Medicaid program and then over billed the program. The company allegedly billed for supplying children with specialized, expensive enteral nutritional formulas but actually dispensed either much less expensive over-the-counter nutritional supplements or nothing at all. The owner is charged with health care fraud in the first degree and grand larceny in the second degree, welfare fraud in the third degree, and two counts of offering a false instrument for filing in the first degree. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrest-brooklyn-medical-supply-company-owner-allegedly.

Oxford Settles Suit Amid Allegations It Improperly Denied Infusion Services—February 23, 2017—Oxford Health Plans and Oxford Health Insurance, Inc. agreed to re-examine its practices and paid $35,000 to the State of New York to redress its wrongful denials of coverage for infusion services in its small group health plans. Oxford members noticed that they began receiving bills for previously covered infusion services, but when contacted, Oxford asserted that these individuals' plan benefits had changed, which was untrue. After the Attorney General's office began its investigation and Oxford acknowledged its error, it persisted in improperly denying benefits. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-oxford-health-improperly-denying-claims-hundreds.

Suffolk County Doctor Convicted for Criminal Sale of Opioid Prescriptions—January 27, 2017—A Long Island doctor was convicted on felony charges for selling prescriptions for narcotics and other controlled substances. The doctor sold these prescriptions to individuals who paid him in cash for office visits that allegedly never occurred. The case was adjourned to March 2017 for sentencing, and the doctor faces up to 15 years in prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-conviction-

suffolk-county-doctor-criminal-sale-opioid.

Computer Manufacturer Settles After Data Breach Exposed More Than 35,000 Credit Card Numbers—January 26, 2017—A computer manufacturer based in Taiwan has agreed to pay $115,000 in penalties and maintain reasonable security policies to protect consumer personal information after a data breach of its website exposed over 35,000 credit card numbers. An investigation determined that customer information was not protected for nearly a year, during which time at least one attacker made requests for customer data compromising credit card information. As part of the settlement, the computer manufacturer has agreed to take detailed steps to reform its data security policies. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-computer-manufacturer-after-data-breach-exposed.

Mother and Son Plead Guilty to Consumer-Directed Program Medicaid Fraud—January 25, 2017—A Utica woman and her son pled guilty to stealing over $5,000 in Medicaid benefits through a Consumer Directed Personal Assistance Program intended to allow disabled individuals to remain in their homes and live independently while receiving services. Under the program, the woman selected her son as her home care provider. Her son submitted false timesheets and collected a check for services he never provided, and then split the proceeds with his mother. Both the mother and son will be jointly responsible for the full amount of the theft. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-pleas-mother-son-team-allegedly-defrauding-medicaid.

Binghamton-Area Transport Company Owner Pleads Guilty For Obtaining Over $100K From Medicaid Without Required Taxi Licenses—January 25, 2017—The owner of a taxi company in Broome County pled guilty to grand larceny in the third degree and faces up to seven years in prison for obtaining money from the Medicaid system while illegally operating his business. The defendant transported Medicaid beneficiaries to medical appointments and accepted Medicaid payments during a time period where his company did not possess required taxi licenses. Sentencing is scheduled in March 2017. https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-binghamton-area-transport-company-owner-stealing.

Anthem Agrees to Discontinue Pre-Authorization for Opioid Addiction Treatment Drugs—January 19, 2017—Anthem, the second largest health insurer in the country, agreed to stop requiring pre-authorization for medication-assisted treatment ("MAT") for opioid use disorder. This agreement was reached only several months after a similar agreement was reached with Cigna. Under Anthem's prior policies, providers had to submit prior approval forms for MAT coverage requests, which could cause a delay in treatment or rejection of coverage. Under the agreement, Anthem, which includes Empire BlueCross BlueShield, will discontinue this policy and launch an initiative to expand access to MAT for members in New York. https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-anthem-discontinue-pre-authorization

Drug Manufacturer Settles Suit for Illegally Acquiring Rights to Competitor Drug—January 18, 2017—A drug manufacturer settled a lawsuit that alleged that it acted to prevent competition for its drug, Athcar, that is used to treat life-threatening diseases, including infantile spasms. The drug manufacturer purchased rights to another drug, Synacthen, which is used to treat the same conditions. The company had increased the price of Athcar 85,000% from $40 per vial to over $34,000 per vial, while Synacthen was only a fraction of the price in Europe and Canada. A joint investigation found that the company illegally acquired rights to the competitor drug, Synacthen, in an attempt to monopolize the market. Under the settlement, the company will pay $100 million and will have to license the rights it acquired to Synacthen to a competitor. https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-drug-manufacturer-engaging-anticompetitive.

New York Joins 19 Other States in Pharma Antitrust Lawsuit—December 15, 2016—New York has joined in a federal lawsuit accusing several generic drug makers of conspiring to inflate the prices of two generic drugs: doxycycline hyclate delayed release, an antibiotic, and glyburide, a diabetes medication. The suit originated with a 2014 Connecticut investigation into suspicious price increases for generic drugs, and alleges that drug companies colluded with competitors at trade shows, customer conferences, and other events as well as through direct communications to fix prices, divide up the marketplace, and inflate the price of drugs. https://ag.ny.gov/press-release/ag-schneiderman-files-federal-antitrust-lawsuit-19-other-states-against-heritage.

Medicaid Program Overpaid CHHAs $16.6 Million Between May 1, 2012 and December 31, 2015—December 8, 2016—The Department of Health inappropriately paid millions to Certified Home Health Agencies, including payments made for home health beneficiaries who were transferred into Managed Long-Term Care programs during their 60-day care episodes, payments for multiple episodes for the same recipient within a 60-day period, and payments for a full 60 days when the beneficiaries were transferred to other CHHAs during that time. The Office of the State Comptroller determined that the Department did not have controls in place to identify and prevent overpayments like these. http://www.osc.state.ny.us/press/releases/dec16/120816.htm.

Bristol-Myers Squibb Settles Abilify Suit for $19.5 Million—December 8, 2016—Bristol-Myers Squibb settled a lawsuit brought by 41 attorneys general concerning its marketing of Abilify, an atypical antipsychotic medication. The pharmaceutical company allegedly promoted the use of Abilify among elderly and pediatric patients by misrepresenting and minimizing the risks and side effects of the drug. These risks included metabolic changes, weight gain, and an increased risk of death among elderly patients with dementia-related psychosis. https://ag.ny.gov/press-release/ag-schneiderman-announces-195-million-multi-state-agreement-bristol-myers-squibb-end.

Department of Health Improperly Paid $6.8 Million in Medicaid Claims from October 2015 through March 2016—November 30, 2016—The New York State Office of the State Controller found that the New York State Department of Health improperly paid millions of dollars in improper reimbursements for Medicaid claims, including more than $3.5 million in overpayments for fee-for-service claims submitted for beneficiaries who are enrolled in managed care plans. Auditors also discovered more than a dozen providers enrolled in the program had been charged with or found guilty of crimes that exclude them from participation in the Medicaid program. http://www.osc.state.ny.us/press/releases/nov16/113016.htm.

Arrest in Sham Substance Abuse Treatment Services Scheme—November 29, 2016—An individual and two corporate entities were indicted for grand larceny, health care fraud, and money laundering in an alleged scheme to operate a sham substance abuse treatment program. The defendant and her co-conspirators allegedly paid Medicaid beneficiaries kickbacks and offered them suboxone prescriptions to convince them to enter an illusory treatment program. Patients in the program never received legitimate substance abuse treatment, but rather were enrolled in a particular Medicaid managed care organization and prescribed more suboxone. Some patients were later induced to sell their suboxone prescriptions back to the program for cash. The sham program then billed Medicaid for a variety of medical services that were never rendered. https://ag.ny.gov/press-release/ag-schneiderman-announces-indictment-and-arraignment-clinic-operator-allegedly.

Guilty Plea in Consumer-Directed Personal Assistance Program Fraud—November 18, 2016—A Rochester-area man pled guilty to falsifying home health aide records as part of the Consumer-Directed Personal Assistance Program, after allegedly hiring his girlfriend as a home health aide for a Medicaid recipient who designated the man as a self-directing other. The man approved of time sheets for 502 hours of services that were not actually provided, either because the would-be aide was working at another job or the Medicaid recipient was in an adult day care program. The man pled to grand larceny in the fourth degree. https://ag.ny.gov/press-release/ag-schneiderman-announces-larceny-plea-rochester-man-billing-medicaid-aide-services.

CNA Receives Weekend Incarceration, Probation for Punching Nursing Home Resident—November 17, 2016—A Utica certified nurse aide pled guilty to endangering the welfare of a vulnerable elderly person or incompetent or physically disabled person in the second degree, admitting that she punched an 87-year-old nursing home resident in the face, fracturing his nose and the bones around his eye. The aide was sentenced to four months of weekend incarceration and five years' probation. https://ag.ny.gov/press-release/ag-schneiderman-announces-jail-time-nursing-home-aide-who-punched-resident.

Long Island Radiology Practice Settles $8 Million False Claims Act Suit—November 16, 2016—A radiology practice agreed to pay over $8 million to resolve allegations that the practice submitted false claims to Medicare and Medicaid between 2003 and 2015. The practice allegedly submitted bills in one physician's name although other physicians not enrolled in Medicaid or Medicare actually performed the billed services. The practice also allegedly performed x-rays and ultrasounds automatically on certain patients, even when physicians did not order the tests. https://ag.ny.gov/press-release/ag-schneiderman-announces-joint-state-and-federal-8-million-civil-settlement-long.

Drug Treatment, "Three-Quarter" House Owners Arrested Amid Kickback Allegations—November 11, 2016—An owner of two substance abuse treatment programs and two "three-quarter" house owners were arrested in an alleged scheme to pressure residents in three-quarter homes to attend drug treatment programs. All defendants were charged with grand larceny in the first degree, money laundering in the second degree, and violation of Social Services Law § 366(d). The three-quarter house owners were previously indicted for a kickback relationship with a separate substance abuse treatment program, and currently await trial. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrest-long-island-attorney-and-operators-three-quarter.

United Health Care Improperly Retained Drug Rebate Revenue—November 1, 2016—According to the New York State Office of the State Controller, United Health Care, which administers the New York State Health Insurance Program's Empire Plan, failed to remit nearly $1.5 million in prescription rebates that its subcontractor, Express Scripts, improperly withheld between 2010 and 2013. Under its contract with the State, United and its subcontractors were required to remit 100% of all manufacturer rebates for prescriptions to the State. http://www.osc.state.ny.us/press/releases/nov16/110116.htm.

Long Island Pharmacist Sentenced for Selling over $274 Million in Diverted HIV Medication—October 26, 2016—A pharmacist was sentenced to 8–24 years in state prison and ordered to provide repayment of $25.2 million stemming from a scheme to dispense black-market HIV medication to Medicaid recipients. The pharmacist purchased drugs on the street that were then repackaged and resold to a pharmacy, which then dispensed the drugs to patients. The pharmacy compliance officer, who accepted $5 million to accept the diverted drugs, was previously sentenced to 2–6 years in state prison. https://ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-long-island-pharmacist-24-years-prison-selling.

Cigna Agrees to Discontinue Pre-Authorization for Opioid Addiction Treatment Drugs—October 21, 2016—Cigna agreed to stop requiring pre-authorization for medication-assisted treatment ("MAT") for opioid use disorder. Preauthorization previously caused delays of several days before providers could prescribe MAT medications, including buprenorphine or naloxone, which are used to treat opioid addiction. MAT medications can be dispensed and administered in physician offices, rather than in clinic environments, which lowers barriers to delivering these treatments to patients. https://ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-cigna-discontinue-pre-authorization.

Physician Jailed for Selling Oxycodone Prescriptions—October 20, 2016—A Long Island internist was sentenced to six months' incarceration and five years' probation for selling oxycodone prescriptions. The physician pled guilty to Criminal Sale of Prescriptions for a Controlled Substance as well as 4th Degree Criminal Tax Fraud in May 2015. The physician admitted that he charged patients with substance use issues $250 for prescriptions, and did not take their medical histories, examine them, or conduct any tests before writing the prescription. The physician lost his medical license in August of 2016. https://ag.ny.gov/press-release/ag-schneiderman-announces-jail-sentence-long-island-doctor-selling-prescriptions.

CNA Sentenced to Weekend Incarceration, Probation for Pushing Nursing Home Resident—October 19, 2016—A Certified Nurse Aide who struck a nursing home resident in the face and pushed him to the ground was sentenced to four months of weekend incarceration with five years' probation for Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree. The resident suffered a shoulder injury as a result of the altercation. https://ag.ny.gov/press-release/ag-schneiderman-announces-jail-time-aide-who-struck-shoved-nursing-home-resident.

Six People Arrested for Stealing from Nursing Home Residents—October 18, 2016—Six individuals, five of whom were caretakers in varying capacities, were arrested for stealing from nursing home residents. Four of those charged used residents' bank accounts or credit cards or diverted resident spending money for their own use. Among the arrested individuals were a finance clerk, a director of social services, and a director of social work. One alleged perpetrator accompanied a resident with memory and cognitive deficits to a bank where she allegedly learned his PIN, and later stole hundreds of dollars from his account, including one withdrawal made after the resident's death. https://ag.ny.gov/press-release/ag-schneiderman-announces-arrests-six-individuals-allegedly-stealing-nursing-home.

Omnicare Settles Depakote Fraud Allegations for $28.125 Million—October 17, 2016— Omnicare settled a federal lawsuit, in which several states attorneys general joined, to resolve allegations that it accepted kickbacks from Abbott Laboratories to promote and purchase Depakote, a drug used to treat seizure disorders, bipolar disorder, and migraines. Abbott settled a related lawsuit for $12 million in 2012. https://ag.ny.gov/press-release/ag-schneiderman-announces-28125m-national-healthcare-fraud-settlement-omnicare.

The New York State Medicaid Program Overpaid MCOs More Than $18.9 Million for 2014–2015—October 13, 2016—The Office of the State Comptroller found that the Department of Health overpaid MCOs because of a flaw in rate-setting methodology, which led the Department to improperly cover taxes that MCOs never paid, and in some cases paid for administrative and marketing expenses that should not have been covered. The Department also failed to assess $38.6 million in contracted actuarial costs against the MCOs, which it is required by law to do. http://www.osc.state.ny.us/press/releases/oct16/101316.htm.

Physician Repays $500,000 for Fraudulent Office Visits—October 6, 2016—A Rochester-area physician pled guilty to misdemeanor falsification of business records and paid $500,000, and his medical practice pled guilty to felony grand larceny in the third degree. The physician and practice billed for services that the doctor did not provide and that ineligible staff provided, and overbilled for various services. https://ag.ny.gov/press-release/ag-schneiderman-announces-recovery-over-500k-local-doctors-fraudulent-medicaid.

Medical Equipment Provider Pleads Guilty in $2 Million Medicaid Fraud—September 30, 2016—For more than six years, a now-defunct durable medical equipment company in Huntington submitted thousands of false claims to the Medicaid program, resulting in a $2 million overpayment. The owner pled guilty to Grand Larceny in the second degree, and admitted to billing Medicaid for medical equipment that was never ordered or received, and to falsifying numerous records, including prescriptions and business records to cover up the overbilling.

https://ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-owner-suffolk-county-medical-equipment-store.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

OIG Fraud Alert: HHS OIG Hotline Telephone Number Used in Scam—March 3, 2017—https://www.omig.ny.gov/latest-news/1031-oig-fraud-alert-hhs-oig-hotline-telephone-number-used-in-scam.

Former Brooklyn Clinic Owner Sentenced for Role in $70 Million Medicaid and Medicare Fraud Scheme—March 1, 2017—https://www.omig.ny.gov/latest-news/1030-former-brooklyn-clinic-owner-sentenced-for-role-in-70-million-medicaid-and-medicare-fraud-scheme.

Brooklyn Clinic Manager Pleads Guilty in $55 Million Medicaid and Medicare Scheme—February 27, 2017—https://www.omig.ny.gov/latest-news/1028-brooklyn-clinic-manager-pleads-guilty-in-55-million-medicaid-and-medicare-scheme.

OMIG Assists in $2.1 Million Medicaid and Medicare Fraud Scheme Takedown—February 27, 2017—https://www.omig.ny.gov/latest-news/1029-omig-assists-in-2-1-million-medicaid-and-medicare-fraud-scheme-takedown.

Continuing Legal Education Credit Now Available for OMIG Webinar # 36— February 23, 2017—https://www.omig.ny.gov/latest-news/1024-continuing-legal-education-credit-now-available-for-omig-webinar-36.

OMIG Provides Best Practices and Key Recommendations for White Paper Targeting Opioid Epidemic—January 25, 2017—https://www.omig.ny.gov/latest-news/1021-omig-provides-best-practices-and-key-recommendations-for-white-paper-targeting-opioid-epidemic.

OMIG Assists in $33 Million Medicaid and Medicare Fraud Scheme Takedown— January 13, 2017—https://www.omig.ny.gov/latest-news/1019-omig-assists-in-33-million-medicaid-and-medicare-fraud-scheme-takedown.

Reminder of Certification Requirement for Compliance Programs and DRA Obligations—December 21, 2016—https://www.omig.ny.gov/latest-news/1014-reminder-of-certification-requirement-for-compliance-programs-and-dra-obligations .

Compliance Certification Requirements—December 1, 2016—https://www.omig.ny.gov/compliance/certification

OMIG Investigation Helps Lead to a Larceny Plea by a Rochester Man for Fraudulently Billing Medicaid—November 23, 2016—https://www.omig.ny.gov/latest-news/1006-omig-investigation-helps-lead-to-a-larceny-plea-by-a-rochester-man-for-fraudulently-billing-medicaid-11212016.

OMIG's Investigative Efforts Help Lead to Conviction of Brooklyn Pharmacist Who Illegally Distributed Oxycodone—November 14, 2016—https://www.omig.ny.gov/latest-news/1003-omig-s-investigative-efforts-help-lead-to-conviction-of-brooklyn-pharmacist-who-illegally-distributed-oxycodone.

OMIG Compliance Program Review Guidance—October 26, 2016—https://omig.ny.gov/images/stories/compliance/compliance_program_review_guidance.pdf.

OMIG Investigative Efforts Play Key Role in Conviction and Sentence of Counterfeit HIV Drug Mastermind—October 26, 2016—https://www.omig.ny.gov/latest-news/988-omig-investigative-efforts-play-key-role-in-conviction-and-sentence-of-counterfeit-hiv-drug-scheme-mastermind.

Endnote

1. The decisions are summarized after they are posted on the Department of Health's website, which is often many months after the date of the decision.

In the Law Journals

By Mishka Woodley

Analyzing Social Impairments Under Title I of the Americans with Disabilities Act, Susan Carle, 50 U.C. Davis L. Rev. 1109 (2017).

Bad Medicine: Parents, the State, and the Charge of "Medical Child Abuse," Maxine Eichner, 50 U.C. Davis L. Rev. 205 (2016).

Biotechnology and Consumer Decision-Making, Joanna Sax, 47 Seton Hall L. Rev. 433 (2017).

Determining the Deception of Sexual Orientation Change Efforts, John Satira, 58 Wm. & Mary L. Rev. 641 (2016).

Evaluating NFL Player Health and Performance: Legal and Ethical Issues, Jessica Roberts, I. Cohen, Christopher Deubert & Holly Lynch, 165 U. Pa. L. Rev. 227.

Federalism and the End of Obamacare, Nicholas Bagley, 127 Yale L.J. 1 (2017).

Genetic Property, Jorge L. Contreras, 104 Geo. L.J. 1 (2016).

Gridlock, Josh Blackman, 130 Harv. L. Rev. 241 (2016).

Informed Consent for the Use and Storage of Residual Dried Blood Samples from State Mandated Newborn Genetic Screening Programs, Tufik Shayeb, 64 Buffalo L. Re. 1017 (2016).

Mature Minors, Medical Choice, and the Constitutional Right to Martyrdom, Josh Burk, 102 Va. L. Re. 1355 (2016).

Of Mosquitoes, Adolescents, and Reproductive Rights: Public Health and Reproductive Risks in a Genomic Age, Luke Haqq, 101 Minn. L. Rev. 827 (2016).

Private Enforcement of the Affordable Care Act: Toward an "Implied Warranty of Legality" in Health Insurance, Christine Monahan, 126 Yale L.J. 1118 (2017).

Reproductive Negligence, Dov Fox, 117 Colum. L. Rev. 149 (2017)

Reproduction Reconceived, Courtney Cahill, 101 Minn. L. Rev. 617 (2016)

Retaliatory RICO and the Rule of Fraudulent Claiming, Nora Engstrom, 115 Mich. L. Rev. 639 (2017)

Seeing Voices: Potential Neuroscience Contributions to a Reconstruction of Legal Insanity, Jane Moriarty, 85 Fordham L. Rev. 599 (2016)

The Close of High Prices: Embedding an Ethic of Expense into the Standard of Care, Isaac Dd. Buck, 58 B.C. L. Rev. 102 (2017)

The DNA Default and Its Contents: Establishing Modern Parenthood, Katharine Baker, 96 B.U.L. Rev. 2037 (2016)

The Forgotten Rule of Professional Conduct—Representing a Client with Diminished Capacity, Barry Kozak, 49 Creighton L. Rev. 827 (2016)

The Intersection of Contract Law, Reproductive Technology, and the Market: Families in the Age of Art, Deborah Zalesne, 51 U. Rich. L. Rev. 419 (2017)

The "M" in MLP: A Proposal for expanding the Roles of Clinicians in Medical-Legal Partnerships, Jesselyn Friley, 126 Yale L.J. 1225 (2017)

Trial and Error: Legislating ADR for Medical Malpractice Reform, Lydia Nussbaum, 76 Md. L. Rev. 247 (2017)

Symposia

A Perspective on the Potential Role of Neuroscience in the Court, Ruben Gur, Oren Gur, Arona Gur, and Alon Gur, 85 Fordham L. Rev. 547 (2016)

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Psychiatric Advance Directives: A New York Perspective

By Ronna Blau, Lisa Volpe, Christy Coe and Kathryn Strodel

Psychiatric advance directives are relatively new legal instruments that may be used to document a competent person's specific instructions or preferences regarding future mental health treatment. Psychiatric advance directives can be used to plan for the possibility that someone may lose capacity to give or withhold informed consent to treatment during acute episodes of psychiatric illness.[1]

I. INTRODUCTION

It is a firmly established principle in New York common law that every individual of adult years and sound mind has a right to determine what shall be done with his own body[2] and to control the course of his medical treatment.[3] Patient autonomy and self-determination are basic tenets of New York law that have been faithfully adhered to by courts[4] and codified in various statutes governing informed consent and health care decision making.[5] The priority of the patient's decision is a firmly ensconced principle in New York State law.[6]

As medical technology advanced it became clear, however, that there was a need for consistent decision making procedures for patients who lost decision making capacity. Beginning with California in 1976, all states enacted advance directive statutes of some sort, including either living wills (containing instructions about particular treatments and medical conditions) or durable powers of attorney (appointing a surrogate decision maker) or both.[7] In 1990, the federal Patient Self-Determination Act (PSDA) was enacted to promote the use of written advance directives.[8] Passage of the PSDA followed the United States Supreme Court June 25, 1990 decision in *Cruzan v. Director, Missouri Department of Health.*[9] Writing for a divided Court in a 5-4 opinion, Chief Justice Rehnquist determined, among other things, that the United States Constitution did not forbid Missouri from requiring that there be clear and convincing evidence of an incompetent patient's wishes relative to the withdrawal of life-sustaining treatment.[10]

The PSDA requires health care facilities receiving federal funds to inform patients of their rights under state law to prepare an advance directive, to inquire and document whether patients have executed a directive, to ensure compliance with state laws by respecting advance directives, and to educate health care providers regarding these legal instruments.[11] The same year the federal PSDA was enacted, New York amended its Public Health Law (PHL) to permit a patient with capacity to appoint a health care agent.[12] Codified at article 29-C of the PHL, the health care proxy statute was in derogation of the common law which, similar to the State of Missouri, did not permit a third person to make a decision to forgo life sustaining treatment on behalf of a patient lacking decision-making capacity in the absence of clear and convincing evidence of the patient's prior competent choice.[13] There is no legislation in New York expressly authorizing living wills, but they are recognized under the common law and health and mental health regulations[14] as evidence of the patient's intentions pertaining to the rendition or withholding of treatment. Moreover, New York's Family Health Care Decisions Act provides that there is no need to seek a surrogate decision about treatment, including life-sustaining treatment, if the patient already made the decision expressed in writing, which would include a living will.[15]

While legal scrutiny in New York has been afforded primarily to life sustaining treatment cases,[16] a legally authorized surrogate, such as a health care agent, is empowered to make any and all health care decisions on the principal's behalf that the principal could make.[17] This legal principle becomes particularly relevant when examining the use of psychiatric advance directives.[18] Courts have long recognized that all patients, including patients with severe mental illness, have the right to participate meaningfully in the course of their own treatment, to be free from unnecessary or unwanted medication, and to have their rights of personal autonomy and bodily integrity respected by agents of the state.[19]

A person is not deemed incapable of making medical decisions by simply virtue of a psychiatric diagnosis. Nonetheless, a mental illness may render a person temporarily unable to make informed choices regarding his or her care and treatment.[20] Psychiatric advance directives (PADs) were introduced as a means for people with psychiatric conditions to retain choice and control over their own mental health treatment during periods of decisional incapacity.[21] A PAD can be "instructive" enabling a person to specify treatment to be administered or refused when incapacitated, or take the form of a proxy directive permitting patients (principals) to appoint a representative to make health care decisions, or a combination of both.[22] Notably, the Center for Medicare and Medicaid Services (CMS) endorses the use of the PAD, recognizing that a PAD is akin to a traditional advance directive for health care. Further, CMS recommends that a PAD be accorded the same respect and consideration that a traditional advance directive for health care is given even where state law has not explicitly sanctioned their use.[23]

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II. A COMPARISON OF PAD STATUTES OF OTHER STATES AND THE NEW YORK HEALTH CARE PROXY LAW

Article 29-C of the Public Health Law makes no distinction between a health care agent's authority to make medical decisions and the authority to make mental health elections on behalf of a principal deemed to lack capacity. Health care for purposes of New York's statute is, in fact, defined as any treatment, service or procedure to diagnose or treat an individual's physical or mental condition.[24] In contrast, some states have specialized PAD statutes.[25] A PAD executed in another state or jurisdiction in compliance with the law of that state or jurisdiction shall be considered validly executed for purposes of New York law.[26] While New York is a general advance directive state, PAD forms are in use and available on line.[27] Research suggests that although 70% of patients with mental illness would want a PAD if offered assistance completing one, less than 10% have actually executed a PAD.[28] The literature is replete with analyses related both to the benefits and shortcomings of the PAD and confusion about the utility of PADs may be contributing to their underutilization in practice.[29]

Whether executed in an express PAD jurisdiction or in a general advance directive state such as New York, there are many benefits associated with PADs. These benefits include the potential to empower individuals with mental illness relative to their treatment choices, increase their satisfaction, motivation and treatment adherence, enhance continuity of care, promote early intervention and preventative care, encourage treatment collaboration and communication between the patient, family and clinical team, decrease reliance on coercive measures, assist in crisis de-escalation, and decrease hospitalization and the need for judicial intervention to compel treatment.[30]

Potential problems with PADs include insufficient education regarding the role of these instruments and the formalities associated with their execution as well as misunderstandings among clinical staff and providers regarding the utility of PADs. There are questions surrounding legality and liability, especially when a person elects to create a PAD to refuse treatment seen as critical in a crisis. There is also the potential for stigmatizing people with mental illness using distinct psychiatric advance directives (with their related rules and susceptibility to override by physicians) as somehow different from patients with cognitive impairments who complete general health care advance directives.[31] With respect to this latter pitfall, the potential for physician override of a PAD is perhaps the most controversial aspect of these advance planning tools.[32] In addition, there is little guidance on how laws governing mental health advance directives and civil commitment statutes are to be reconciled with one another.[33]

In states with PAD statutes, physician override of a PAD may be permitted under the following circumstances:

- where there is a court order finding incapacity;
- in case of emergency involving imminent threat of harm to the mental health service recipient or others; or where PAD instructions have not been effective in reducing the severity of the behavior causing the emergency; or, in an emergency where there is substantial risk of death or immediate and serious harm to the patient and within a reasonable degree of medical certainly the individual's health and safety would be affected adversely by delaying treatment;
- where there is a court order that contradicts the PAD instructions;
- where there is a court order authorizing involuntary commitment;
- where there is substantial evidence that failure to override would result in harm to the principal;
- if, in the opinion of the mental health professional, compliance with the PAD instructions is not consistent with generally accepted community standards of treatment, or the requested treatment is medically ineffective;
- if compliance is not consistent with court-ordered treatment.[34]

To date, the only reported decision interpreting a mental health advance directive statute in the commitment context is *Hargrave v. State of Vermont*.[35] In *Hargrave*, the Second Circuit Court of Appeals examined the validity of a Vermont statute that was alleged to violate the Americans with Disabilities Act (ADA). Pursuant to Vermont law, a civilly committed or imprisoned patient's previously executed durable power of attorney for psychiatric treatment preferences could be overridden through a petition by a health care professional to involuntarily medicate the patient. However, the procedure available to other incapacitated patients in Vermont allowed for a durable power of attorney for medical treatment preferences to be overridden in only two distinct circumstances; i.e., by the patient's revocation of the power of attorney or by a third party's petition to suspend the power of attorney in conjunction with the appointment of a guardian for the individual. According to the challenged statute, the committed patient's previously executed durable power of attorney would be honored for 45 days, during which the facility would observe any improvement to the patient's condition in the absence of the rejected medication. If no improvement appeared, the court would determine whether to forcibly administer the medication pursuant to the health care professional's petition. Plaintiff argued that the more relaxed override provisions pertaining to individuals with mental illness who were otherwise qualified to execute durable powers of attorney was discriminatory and violated the ADA.

The state-defendants in *Hargrave* invited the appeals court to hold that the initial judicial determination of dangerousness at the time of civil commitment was sufficient to exclude otherwise qualified mentally ill people from the protections of the ADA permitting the durable powers of attorney to be overridden. Specifically, the defendants maintained that the "direct threat" exception[36] of the ADA applied and that the exception continued for the entire length of the patient's commitment. The Second Circuit Court of Appeals ruled in favor of the plaintiff, however, concluding that the ADA's direct threat exclusion was inapplicable because Vermont failed to demonstrate that every civilly committed person subject to the statute's abrogation procedures posed a direct threat of harm to others sufficient to exclude her from the protections of the ADA.

The conclusion rested on two principles. First, the court observed that civil commitment in Vermont was based on a finding that the individual poses a danger to self or others, whereas the direct threat defense under the ADA requires the person to pose a risk of harm to *others*. Second, the court emphasized the significant delay in time between the initial civil commitment and abrogation of the durable power of attorney and the lack of an individualized hearing prior to the latter. By virtue of these findings, and others, the Second Circuit held that the Vermont statute impermissibly discriminated against qualified individuals who meet the essential eligibility requirements for maintaining durable power of attorneys and enjoined enforcement of the statute.

Given the decision in *Hargrave*, it appears that PAD-specific laws of other jurisdictions that permit a physician or court to override a person's prior capacitated choice are susceptible to challenge under the ADA. In contrast to Vermont, New York's health care proxy statute does not distinguish between medical and mental health treatment decisions and does not contain specific abrogation provisions. Absent conscience objections, a health care provider is obligated to comply with health care decisions made by an agent in good faith under a health care proxy to the same extent as if such decisions had been made by the principal.[37] Thus, the only limitations on the enforcement or revocation of advance mental health treatment directives in New York are potentially found in the state's civil commitment statutes,[38] under the common law[39] or under article 29-C itself which does not permit a health care proxy to be revoked by a principal determined by a court of law to be incompetent.[40] However, no reported decision in New York has squarely addressed these issues. The literature suggests that to survive scrutiny under the ADA, overriding PAD instructions can occur when the directive poses a direct threat to the health or safety of others or where there is a direct threat to the patient's life caused by a mental health emergency.[41] An individualized dangerousness assessment at the time of abrogation is also likely required to conform to the ADA.[42]

Also implicated in New York are statutory and regulatory strictures which must be satisfied before a health care proxy may be executed or revoked. In this regard, if a person executes a health care proxy while resident in a facility licensed or operated by the Office of Mental Health or the Office for People with Developmental Disabilities, witnesses to the proxy must have special clinical credentials.[43] The witnessing requirements are intended to ensure that the patient has capacity to execute the advance directive. Further, as provided for at section 2985 of the PHL, a competent adult may revoke a health care proxy by notifying the agent or a health care provider orally or in writing or by any other act evidencing a specific intent to revoke the proxy. For purposes of the statute, every adult shall be presumed competent unless determined otherwise pursuant to court order. Of course, in New York, only in rare instances do plenary adjudications of incompetence survive and thus, even a person with a legal guardian retains all powers and rights except those powers and rights which the guardian is granted[44] and thus, may be able to revoke a health care proxy or execute a new one.[45]

"Our state statute further provides certain safeguards to protect an individual's ability to challenge an unwanted health care decision even if she has been deemed incapacitated, thus, in effect, circumventing the inability to revoke."

Our state statute further provides certain safeguards to protect an individual's ability to challenge an unwanted health care decision even if she has been deemed incapacitated, thus, in effect, circumventing the inability to revoke. Section 2983 of the PHL provides, for instance, that notwithstanding a determination pursuant to this section that the principal lacks capacity to make health care decisions, where a principal does object to the determination of incapacity or to a health care decision made by an agent, the principal's objection or decision shall prevail unless the principal is determined by a court of competent jurisdiction to lack capacity to make health care decisions. Moreover, our state law permits the commencement of a special proceeding to resolve disputes arising under the law.[46] In the opinion of the authors, a principal's potential inability to revoke a health care proxy in the event of future incapacity should not dissuade the person from executing a PAD, nor outweigh the value of a PAD that expresses treatment wishes based upon past experiences and an understanding of treatment options. Furthermore, in a judicial proceeding, the treatment preferences articulated in a PAD would likely constitute clear and convincing

evidence of the individual's preferences and wishes, thus providing the court with a basis to determine whether a proposed treatment is appropriate for a person who has lost decisional capacity.

A concomitant issue is whether the mental health directives expressed in a PAD document could defeat a *Rivers* application commenced to override a patient's objection to the administration of psychiatric treatments.[47] It might be argued that if a *Rivers* application is commenced invoking the *paren patriae* powers of the state, a judicial override of PAD instructions can only occur upon an individualized finding of dangerousness to survive scrutiny under the ADA.[48] While a hospital cannot be prevented from commencing a *Rivers* proceeding, a PAD which contains articulated reasons for definitely expressed treatment preference may be instructive to fact finders. That is, the PAD may be used at both the administrative review preceding the *Rivers* application[49] and in court to aid the judge in narrowly tailoring any involuntary treatment order to give substantive effect to the patient's liberty interest.[50] At the very least, the PAD offers clear and convincing evidence of the patient's treatment preferences expressed at a time when the individual had the capacity to make treatment decisions that should be honored by the hospital and the court.

III. CONCLUSION

While New York does not have a specific mental health advance care directive statute, Article 29-C of the PHL provides for the appointment of a single health care agent empowered to make both medical and mental health care decisions. A principal is also permitted to include instructions regarding future care within her advance directive. Psychiatric advance directives are a valuable planning tool for people with mental illness. Their execution should be encouraged in order to afford individuals with mental disabilities the greatest autonomy possible in relation to their health care. There is uncertainty in the law as to whether and when a PAD may be overridden and the relationship between the PAD and civil commitment is ill-defined. Nonetheless, the potential for PADs to enhance the effectiveness of mental health treatment and avoid the need for involuntary care and treatment are laudable public health goals that should be pursued through education and outreach.

Endnotes

1 National Resource Center on Psychiatric Advance Directives: www.nrc-pad.org.

2 *Schloendorff v. Society of N.Y. Hosp*., 211 N.Y. 125, 129 (Cardozo, J.).

3 *In re Storar*, 52 N.Y.2d 363; *Schloendorff v. Society of N.Y. Hosp*., 211 N.Y. 125, *supra*).

4 *Rivers v Katz*, 67 N.Y. 2d 485, 492-493, *citing, Matter of Storar,* 52 N.Y. 2d 363, *supra, Matter of Harry M*., 96 A.D.2d 201.

5 PHL 2504, 2805-d.

6 PHL 2983(5), 2994-c (6).

7 Jeffery W. Swanson, PhD, S. Van McCrary, PhD., Marvin S. Swartz, MD., Eric B. Elbogen, PhD., and Richard A. Van Dorn, PhD., *Superseding Psychiatric Advance Directives: Ethical and Legal Considerations,* 34 J. Am. Acad. Psychiatry Law 385, 386 (2006).

8 Codified at 42 U.S.C.A. 1395cc (f).

9 497 U.S. 269. The only other state with such a stringent rule was New York. *See Matter of Westchester County Med. Ctr. (O'Connor)*, 72 N.Y.2d 517.

10 The *Cruzan* majority also determined that state courts did not commit constitutional error in concluding that evidence adduced at trial did not amount to clear and convincing evidence of the patient's desire to cease hydration and nutrition; and finally, that due process did not require state to accept substituted judgment of close family members absent substantial proof that their views reflected those of patient. *See* 497 U.S. at 282-287.

11 42 U.S.C.A. 1395cc (f). Despite the enactment of the PSDA, research suggests that the prevalence of written medical advance directives in the general public remains no higher than 25 percent and did not substantially increase after passage of the federal law. *See* Swanson, *supra* note 7, p 387 and authorities cited therein.

12 L. 1990, c. 752. The legislation was based upon the consensus recommendations of the Task Force on Life and the Law convened by Governor Mario Cuomo in March 1985.

13 *In re Westchester County Med. Ctr. (O'Connor)*, 72 N.Y.2d 517, 530-531 *supra.* In *O'Connor*, the Court of Appeals stated: Every person has a right to life, and no one should be denied essential medical care unless the evidence clearly and convincingly shows that the patient intended to decline the treatment under some particular circumstances.

14 As stated in *O'Connor*, the ideal situation for evidence of a prior competent choice by a patient who now lacks decision making capacity is through a living will (72 N.Y.2d at 532). The existence of a writing suggests the author's seriousness of purpose and ensures that the court is not being asked to make a life-or-death decision based upon casual remarks. Further, a person who has troubled to set forth his or her wishes in a writing is more likely than one who has not to make sure that any subsequent changes of heart are adequately expressed, either in a new writing or through clear statements to relatives and friends. In contrast, a person whose expressions of intention were limited to oral statements may not as fully appreciate the need to rescind those statements after a change of heart (*id*.).

15 PHL § 2994-d.3(a)(ii).

16 *In re Storar*, 52 N.Y.2d 363, *supra; In re O'Connor,* 72 N.Y.2d 517 *supra.*

17 PHL 2982 (1).

18 *See* Judy Ann Clausen, *An Americans with Disabilities Act Critique of Advance Directive Override Provisions,* 71 N.Y.U. Ann. Surv. Am. L. 25, 26 (2015). General advance directives (generic directives) typically address end-of-life care, but mental health advance directives (mental health directives) govern treatment administered during periods of incapacity caused by acute mental illness episodes.

19 *See, e.g. Disability Rights New Jersey, Inc. v. Velez,* 974 F. Supp. 2d 705,709 (2013), *aff'd*, 796 F.3d 293 (3d Cir. 2015).

20 *Rivers v. Katz,* 67 N.Y.2d 485, *supra* note 4.

21 Swanson *et al.*, *supra* note 7.

22 *See* Patricia Backlar, *Anticipatory Planning for Psychiatric Treatment Is Not Quite the Same as Planning for End-of-Life Care*, 33 Community Mental Health J. 261 (1997): *see also,* Clausen, *supra* note 17 at 33-34.

23 CMS State Operations Manual, Appendix A—Survey Protocol, Regulations and Interpretative Guidelines for Hospitals, Interpretive Guideline A -0132 p. 94-95.

24 PHL 2980(4). State law further provides that mental hygiene facilities (and residential heath care facilities) shall establish procedures: (a) to provide information to adult residents about

their right to create a health care proxy; (b) to educate adult residents about the authority delegated under a health care proxy, what a proxy may include or omit, and how a proxy is created and revoked; (c) to help ensure that each resident who creates a proxy while residing at the facility does so voluntarily. *See* PHL 2991 (1).

25 National Resource Center on Psychiatric Advance Directives: www.nrc-pad.org; Clausen, *supra* note 17. The states with specialized PAD statutes are Arizona, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Montana, New Jersey, New Mexico, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, Washington and Wyoming.

26 PHL 2990.

27 See, The Advance Directive Provider Training Project, New York Association of Psychiatric Rehabilitation Services, Planning for Your Mental and Physical Health Care and Treatment, http://www.nrc-pad.org - last visited March 19, 2017.

28 Eric Elbogen, Jeffrey Swanson, Paul Appelbaum, Marvin Swartz, Joelle Ferron, Richard Van Dorn, H. Ryan Wagnor, *Competence to Complete Psychiatric Advance Directives: Effects of Facilitated Decision Making*, 31(3) Law Hm. Bav. 275-289 (2007).

29 *See*, *e.g.*, Clausen, *supra,* note 17; Nat'l Ethics Comm. Veteran's Health Administration, *Advance Directives for Mental Health: An Ethical Analysis of State Laws & Implications for VHA Policy* (Feb. 2008), available on line at www.ethics.va.gov/docs/necrpts/NEC_Report_20080220_Adv_Directives_MH-Analysis of_State_Laws-Implications_for_VHA_Policy.pdf - last visited March 17, 2017.

30 Elbogen et al., *supra* note 27; *see also* U. Penn Collaborative on Community Integration, Psychiatric Advance Directives: Pros, Cons, and Next Steps. tucollaborative.org/pdfs/Toolkits_Monographs_Guidebooks/self_determination_psychiatric_advanced_directives_self_directed_care/Psychiatric_Advance_Directives.pdf, last visited March 17, 2017.

31 *Id.*

32 Swanson et al., *supra* note 7; Paul Appelbaum, *Commentary: Psychiatric Advance Directives at a Crossroads-When Can PADs Be Overridden*, 34 J. Am. Acad. Psychiatry Law 395 (2006).

33 Clausen, *supra* note 17, p. 35. There is no national consensus concerning the interaction of commitment statutes and mental health directives which is one reason why the Uniform Law Commission refrained from enacting a model mental health directive statute. *Id.* at p.37.

34 Clausen, *supra* note 17, p 50-61. In contrast, across jurisdictions, overriding a generic advance directive may occur when the patient's treatment preferences are (1) outside the standard of care; (2) unavailable; (3) medically ineffective; or illegal. *Id* at 49. *See* Uniform Health Care Decisions Act 7(e). 9 U.L.A. 27-28 (2010).

35 340 F.3d 27 (2d Cir. 2003).

36 The ADA does not require an entity to permit an individual to participate in or benefit from the goods, services, facilities, privileges, advantages and accommodations of such entity where such individual poses a direct threat to the health or safety of others. The term "direct threat" means a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures or by the provision of auxiliary aids or services. 42 U.S.C. 12182(b)(3).

37 PHL 2984 (2-4).

38 *See* MHL 9.27, 9.33, 9.37, 9.39.

39 *Rivers v. Katz*, *supra* note 4, 67 N.Y. 2d 485.

40 PHL 2985 (1)(b).

41 Clausen, *supra* note 17, p 75-78.

42 Clausen, *supra* note 17, p 77.

43 PHL 2981 (1)(b)(c): *see also*, 22 NYCRR 22.3 - When a Patient May Sign Legal Instrument.

44 MHL 81.29 (a).

45 Robert Swidler, *Health Care Proxies—Ten Difficult Issues*, 88 N.Y.St. B.J. 28 (July/August 2016).

46 PHL 2992.

47 *Rivers v. Katz*, *supra* note 4, 67 N.Y. 2d 485.

48 Clausen, *supra* note 17, p 77.

49 *See* 14 N.Y.C.R.R. part 527.

50 *Rivers v. Katz*, *supra* note 4, 67 N.Y. 2d at 497–98.

The 21st Century Cures Act: Its Impact on Health Information Privacy and Security Protections

By Linda A. Malek and Jason Johnson

Overview

Congress passed the 21st Century Cures Act ("Act") in December 2016.[1] The Act seeks to modernize and personalize health care while encouraging greater innovation by providing support for clinical research and treatment in several needed areas: "In the 21st century, health care innovation is happening at lightning speed. From the mapping of the human genome to the rise of personalized medicines that are linked to advances in molecular medicine, we have seen constant breakthroughs that are changing the face of disease treatment, management, and cures. Health research is moving quickly, but the federal drug and device approval apparatus is in many ways the relic of another era. We have dedicated scientists and bold leaders at agencies like the NIH and the FDA, but when our laws don't keep pace with innovation, we all lose."[2]

The voluminous Act covers a broad array of topics, focusing on the expansion and acceleration of discovery, development and treatment of new therapies and cures in several areas including cancer, substance abuse and mental health. Although not the main focus, the Act expands existing privacy and security protections for individuals whose health information is used in treatment and clinical research, tries to update relevant law, and requires modifications to existing regulations and guidance to take the current digital environment into account.

The Act passed with strong bipartisan support under the Obama administration. The new administration has proposed a budget that does support some of the initiatives under the Act, while potentially undercutting others. The proposed budget contains an increase in funding for fighting the opioid epidemic of $500 million, one area of the Act's focus, but goes on to propose a $5.8 billion reduction to the NIH's budget.[3] It is unclear how much of the measures proposed and supported by the Act will be affected if the proposed budget is passed. As of the date of this article, the privacy and security protections set forth in the Act remain in effect.

Below is an overview of the provisions of the Act that deal with privacy and security protections for patients and human research subjects and how these changes will affect those involved with patient treatment and human subject research.

I. Act § 2012, Privacy Protection for Human Research Subjects and Act § 2013 Protection of Identifiable and Sensitive Information

Sections 2012 and 2013 expand the scope of privacy and security protections in three ways: (1) by expanding the mandatory use of certificates of confidentiality; (2) by amending the Public Health Service Act to expand the categories of information protected from disclosure under a certificate of confidentiality; and (3) by amending the Freedom of Information Act (FOIA) to expand the classification of what information is protected from disclosure.

Previously the law allowed, but did not require, the issuance of a certificate of confidentiality ("COC") to protect the privacy of individuals involved in government funded research. Generally speaking, a COC allows a researcher to refuse to disclose identifying patient information in the face of compulsory legal demands, such as court orders and subpoenas.[4] Section 2012 makes a COC mandatory for any research funded by the federal government. As before, researchers who are not receiving government funds are still permitted to request a voluntary COC.

The type of information protected under a COC was also expanded under Section 2012. Previously, only "names or other identifying characteristics" were protected.[5] Section 2012 expands information protected to include "identifiable, ***sensitive*** information," which further includes both documentary information and biospecimens, e.g., genetic information. The Act defines "identifiable, sensitive information" as "information that is about an individual and that is gathered or used during the course of research … and (A) through which an individual is identified; or (B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual." The Act specifically indicates these protections are intended to extend to "research on mental health and research on the use and effect of alcohol and other psychoactive drugs."

Sections 2012 and 2013 were originally contained in the Genetic Research Privacy Protection Act (S.2744). Regarding these provisions, co-sponsor Senator Elizabeth Warren stated, "To help to bring forward the next generation of precision medicine, researchers are collecting more and more genetic information. When that genetic information is stored at our nation's research institutions, families should have complete confidence that it will

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remain private."[6] The clarification here that identifiable, sensitive information also includes an individual's genetic information is significant as its inclusion for protection under a COC potentially indicates a move toward further protections of such information in the context of clinical research.

For researchers that receive their funding through government grants, the mandatory COC will require those who did not previously voluntarily comply with COC requirements to implement policies and procedures for the protection of PHI, including identifiable genetic information and to do so in a relatively short period of time. The Act will apply to all current research supported by federal government funds 180 days after the enactment of the Act. Moreover, researchers who already comply with the COC requirements will need to update their internal policies and procedures to ensure that genetic information is also protected from disclosure.

As information collected through government sponsored research is subject to Freedom of Information Act (FOIA) requests, Section 2013 amends FOIA to expand privacy protection to "biomedical information" from disclosure under a FOIA request. In this context, "biomedical information" is considered information "about an individual and that is gathered or used during the course of biomedical research if…an individual is identified; or there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual." Note that the standard for identifiability has to do with current scientific practices or methods. Current scientific methods are making it much easier to turn biomedical information into identifiable information. For example, it has recently been shown that genetic information, along with other publicly available genetic and personal information, can in certain instances be used to identify an individual.[7]

II. Act § 2063, Accessing, Sharing, and Using Health Data for Research Purposes

Section 2063 addresses gaps that exist concerning the use of protected health information ("PHI") remotely, for future research, how authorization can be obtained and withdrawn for such research, and creates a working group to analyze the impacts of research use of PHI under the Health Information Portability and Accountability Act ("HIPAA") regulations.

Section 2063(a) requires the Department of Health and Human Services (HHS) to issue guidance on the remote use of PHI by researchers. In particular, the Act requests that HHS clarify that the privacy regulations promulgated under HIPAA ("Privacy Rule")[8] do not prohibit remote access to health information by a researcher. The Act further requires HHS to issue guidance that expands the Privacy Rule to allow remote access to PHI as long as the covered entity and researcher have privacy and security safeguards consistent with the Privacy Rule and the security regulations promulgated under HIPAA ("Security Rule")[9] and the PHI is not copied or retained by the researcher. Current guidance does not specifically address the remote use of PHI by researchers and having this guidance will facilitate the use of PHI for research purposes among researchers and research institutions.

Currently, the Privacy Rule permits covered entities to use patient PHI without authorization for purposes of treatment, payment and health care operations.[10] The House of Representatives passed a version of the Act in 2015 (H.R. 6)[11] that contained a section that could have expanded the definition of health care operations to include research with health data, which would have significantly broadened the ability of covered entities to use PHI without prior authorization.[12] Section 13443 of H.R. 6 went even further and redefined the term "public health activities" in the Privacy Rule, which do not require authorization, to include information related to the quality, safety or effectiveness of a product or activity regulated by the FDA. This would potentially open up sharing PHI with pharmaceutical and medical device companies without prior authorization. Neither Section appears in the Act. However, Section 2063(a) and Section 2063(b), discussed below, do show that Congress desires broader use of PHI without authorization and is requiring HHS to issue guidance that accomplishes a broader scope of PHI use for research purposes without requiring authorization.

Section 2063(b) requires HHS to issue guidance to clarify what type of authorization is necessary to use PHI for future research and how an individual can revoke such authorization. The ability to obtain authorization for future "unspecified" research was established as part of the modifications to HIPAA that went into effect March 26, 2013 under the final regulations implementing provisions from the 2009 HITECH Act.[13] However, those regulations did not provide detailed guidance from HHS surrounding what constituted a proper authorization for future research and how such authorization may be revoked. The Act recognizes that more detail and clarity is needed in this area and requires HHS to issue clarifying guidance within one year.

Specifically, the Act mandates that guidance issued pursuant to Section 2063(b) should address what information a proper authorization provides, which includes "sufficiently describ[ing] the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research"; either "states that the authorization will expire on a particular date or on the occurrence of a particular event" or "states that the authorization will remain valid unless and until it is revoked by the indi-

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vidual." HHS is also required to clarify the circumstances under which it is appropriate to provide annual notice or a reminder that an individual has a right to revoke authorization and to clarify the appropriate mechanisms to revoke authorization for future research.

Finally, Section 2063(c) requires the creation of a working group, no later than one year after enactment, to study and report on the uses and disclosures of PHI for research purposes under HIPAA. This working group will then submit a report with recommendations on "whether the uses and disclosures of protected health information for research purposes should be modified to allow protected health information to be available, as appropriate, for research purposes, including studies to obtain generalizable knowledge, while protecting individuals' privacy rights." At a minimum the working group report must address the appropriate manner and timing of authorization, including whether additional notifications are necessary; opportunities for an individual to set preferences in how his/her PHI is used in research; opportunities to revoke authorization; breach notifications; law, regulatory and policy gaps related to the protection of PHI; and barriers to research related to the current restrictions on the use of and disclosure of PHI. The working group must consider expectations of PHI use, issues related to specific subgroups, e.g., children, cognitively disabled individuals, relevant federal and state law, models of facilitating data access, potential impacts of disclosure and non-disclosure of PHI on access to health care services and the potential uses of such data. How the working group results will impact future guidance is dependent on how active the new administration is in understanding and regulating the use of PHI.

III. Act § 3024, Informed Consent Waiver or Alteration for Clinical Investigations

Section 3024 provides the United States Food and Drug Administration ("FDA") with flexibility to waive or alter informed consent requirements for clinical testing where the testing "poses no more than minimal risk to human subjects." Prior to the Act, the FDA did not have the power to waive or alter informed consent for minimal risk research. This harmonizes FDA law with the Common Rule, which already provided this flexibility.[14] With this expansion of authority and the Act's push to harmonize regulations surrounding research, it is likely that the FDA will amend its regulations to contain similar provisions to the Common Rule on this issue.

IV. Act § 4001, Assisting Doctors and Hospitals in Improving Quality of Care For Patients

Section 4001 amends Section 13103 of the HITECH Act in an effort to reduce regulatory and administrative burdens, such as documentation, on health care providers relating to the use of electronic health records. To achieve this goal, the HHS Secretary is tasked with developing a strategy and recommendations within one year through "broad public comments" and consulting with experts. One stated priority is recommending incentives for meaningful use of certified electronic health record ("EHR") technology. This section appears to imply an overhaul that focuses on development and adoption of standardized EHR technologies in order to improve patient care.

V. Act § 4003, Interoperability

Section 4003 requires the creation of a trusted network exchange framework to allow the efficient and secure exchange of electronic health information of patients. This framework and a corresponding common agreement must be published within one year. Within two years, a list of health information networks that have adopted the common agreement will be posted on a website. Creating a standard that can be used across platforms will assist in allowing the more efficient exchange of health information in a secure manner.

VI. Act §§ 3002/3003, Health Information Technology Advisory Committee

Section 3002 establishes a Health Information Technology Advisory Committee ("HIT Advisory Committee") that will make recommendations regarding the implementation of a health information technology infrastructure that advances electronic access, exchange and use of health information. The HIT Advisory Committee replaces the HIT Policy Committee and the HIT Standards Committee. The HIT Advisory Committee's role is to provide "standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria."

According to Section 3003, the priority target areas of the HIT Advisory Committee include achieving a health information technology infrastructure that allows for electronic access and exchange of accurate patient records, the promotion and protection of privacy and security of health information in health information technology, and facilitation of secure access to PHI by patients and their family members.

The HIT Advisory Committee will provide annual reports to the HHS Secretary and Congress detailing the work and recommendations made during the last year.

VII. Act § 4006, Empowering Patients and Improving Patient Access to Their Electronic Health Information

Section 4006 focuses on educating health care providers and patients in order to increase patient access to their EHRs. To carry this out, the Act requires HHS to use its existing authority to work with health information exchange organizations and networks, health care providers,

health plans and other appropriate entities to encourage partnerships with the goal of offering patients their electronic health information in an easy to understand, secure format. The idea behind this requirement is that better access to EHRs allows patients more information to use in managing their own healthcare. In addition, the HHS Secretary in coordination with the HHS Office of Civil Rights ("OCR") is required to issue guidance to health information exchanges related to best practices to ensure electronic health information provided to patients is private, secure, accurate, verifiable and easily exchanged pursuant to a patient's authorization.

Section 4006 also supports amending the existing health information technology certification criteria to add certification criteria intended to help support patient's access and usability of their EHR, including adding certification criteria that support patients' access to their electronic health information in an easy to read format; enhancing the patient's ability to electronically communicate information to include in his/her EHR; and giving patients the option to access their personal EHR when they are involved in research.

VIII. Title XI, Compassionate Communication on HIPAA, Act § 11001, Sense of Congress

Major portions of the Act are aimed at addressing issues related to opioid abuse and mental health treatment generally. In Section 11001, Congress recognizes that there is confusion in the healthcare profession regarding the Privacy Rule and disclosing information related to patients with serious mental illness. The Act recognizes that this confusion may hinder appropriate communication regarding treatment or the provision of information to caregivers of those with serious mental illness. As discussed in more detail below, through the Sections contained in Title XI (Sections 11002-11004) Congress requires HHS and OCR to provide clarification regarding existing permitted uses and disclosures of health information by health care providers related to serious mental illness.

A. Act § 11002, Confidentiality of Records

Section 11002 requires the HHS Secretary, within one year of finalizing the regulations updating Part 2 of 42 CFR relating to the confidentiality of alcohol and drug abuse patient records, to hold hearings to determine the effect of these new regulations. This Section is in line with others in the Act to require evaluation of the impact of the new law and regulations and adjust accordingly. This is also in line with Congress' desire, as stated in Section 11001 of the Act, to provide clarification regarding confidentiality of these types of records.

B. Act § 11003, Clarification on Permitted Uses and Disclosures of Protected Health Information and Act § 11004, Development and Dissemination of Model Training Programs

One aspect of mental health treatment is use and access of PHI by physicians and family members or others involved in the treatment of individuals with mental health issues. Obviously, information regarding an individual's substance abuse and mental health issues is highly sensitive. HHS has issued guidance previously on the intersection between the Privacy Rule and sharing of mental health information, which addresses many of the issues described in the Act for HHS to consider.[15] Similar guidance exists for substance abuse, which is issued through the Substance Abuse and Mental Health Services Administration.[16] What the current guidance does not appear to address in depth are issues related to when the patient must provide consent and when a patient should have an opportunity to object. Communication among physicians, family members and other caretakers is critical to the treatment of individuals with addiction or mental health diagnoses.

The Act requires HHS and OCR to ensure that "health care providers, professionals, patients and their families, and others involved in mental or substance use disorder treatment have adequate, accessible, and easily comprehensible resources relating to appropriate uses and disclosures of protected health information under" HIPAA. To accomplish this, Section 11003 requires OCR to issue guidance within one year clarifying the circumstances, consistent with the Privacy Rule, under which a health care provider or covered entity may use or disclose PHI related to treatment of an individual with a mental disorder or a substance use disorder. The guidance must address certain circumstances including when patient consent is required for disclosure, when patients should have an opportunity to object, when professional judgment must be exercised because a patient cannot object, and when professional judgment is exercised because of patient incapacitation. This guidance must also address specific circumstances related to disclosure of PHI regarding various situations involving family members and law enforcement.

Section 11004 requires the HHS Secretary within one year to develop and disseminate, or hire other entities to develop and disseminate, model programs and materials to train health care providers on the permitted uses and disclosures of PHI related to mental disorders or substance use disorder treatment, which should include training on the guidance issues under Section 11003. Congress appropriated $10 million in total for fiscal years 2018-2022 to carry out this Section.

With a key aspect of the Act being to provide resources to better address the treatment of mental health and substance abuse, as well as to expand the use of PHI for such purposes, HHS will need to balance, in its guidance, the protection of this sensitive information and expanding access for treatment purposes.

Conclusion

Although the Act was passed in December of 2016, the issue of privacy protection requirements will continue to evolve as HHS sets about the task of issuing required guidance. Such an effort, along with the working group

reports, is expected to take up to several years. In the meantime, both human subject researchers and covered entities need to be prepared to update and change their privacy protections and their policies and procedures surrounding the use of sensitive identifiable information, including genetic data, mental health information and various forms of PHI.

Endnotes

1. The text of the Act (H.R. 34) can be found at https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf. All Section references throughout this article will refer to this document.
2. See https://energycommerce.house.gov/cures.
3. See https://www.documentcloud.org/documents/3518267-President-Trump-s-proposed-budget.html at pp. 27-28.
4. See https://humansubjects.nih.gov/coc/background.
5. See previous version of Section 301(d) of the Public Health Services Act, at http://legcounsel.house.gov/Comps/PHSA_CMD.pdf.
6. See https://www.law360.com/articles/780889/sens-introduce-bill-to-protect-genetic-information.
7. Gymrek et al., *Identifying Personal Genomes by Surname Inference*, Science, Vol. 339, Jan. 18, 2013, 321–24.
8. See 45 C.F.R. Part 160 and Subparts A and E of Part 164.
9. See 45 C.F.R. Part 160 and Subparts A and C of Part 164.
10. 45 C.F.R. § 164.506.
11. Found at https://www.congress.gov/114/bills/hr6/BILLS-114hr6rfs.pdf.
12. H.R. 6, Section 13442.
13. See 78 Fed. Reg. 5566, 5611–613.
14. See 45 C.F.R. § 46.117.
15. HIPAA Privacy Rule and Sharing Information Related to Mental Health, at https://www.hhs.gov/hipaa/for-professionals/special-topics/mental-health/.
16. "The Confidentiality of Alcohol and Drug Abuse Patient Records Regulations and the HIPAA Privacy Rule: Implications for Alcohol and Substance Abuse Programs, June 2004," at http://www.integration.samhsa.gov/operations-administration/the_confidentiality_of_ alcohol_and_drug_abuse.pdf.

A Proposal to Restore Medical Futility as a Clinical Basis for a DNR Order Under New York Law

By Joseph J. Fins, M.D., M.A.C.P. and Robert N. Swidler, J.D.

Mrs. D, a 91-year-old nursing home resident with dementia, was brought by EMS to the hospital for difficulty breathing. She was diagnosed with bilateral pneumonia, placed on a ventilator, and given antibiotics. After three days her condition deteriorated to multisystem organ failure and sepsis. Her attending physician doubted she would recover, but could not say for sure. But he was certain that if her condition worsened to the point where her heart stopped, resuscitation would be ineffective. Accordingly, he spoke with Ms. D's adult children about a DNR order.

Under New York's former Do-Not-Resuscitate (DNR) Law,[1] which was in effect for 22 years (1988-2010), a physician could write a DNR order for a patient who lacked capacity if he or she determined, among other circumstances, that resuscitation would be "medically futile," another physician concurred, and a surrogate decision-maker consented to the DNR order.[2] If the patient had no surrogate, the physician could write the order based on medical futility without surrogate consent, with the concurrence of another physician.[3]

In 2010, with the enactment of the Family Health Care Decisions Act (FHCDA),[4] the medical futility standard for a DNR orders was superseded by more general criteria for decisions about the withdrawal or withholding of life-sustaining treatment.[5] Overall, the FHCDA has greatly improved care toward the end of life by empowering family decision-makers and establishing clear principles and procedures. But by attempting to create clinical criteria that could apply to all end-of-life decisions, the FHCDA forfeited the helpful specificity of the medical futility standard for DNR decisions, and thereby created problems in clinical practice.

As explained below, end-of-life care would be improved by amending the FHCDA to restore the former "medical futility" standard as one of the alternative criteria for writing a DNR order. These are the views of the authors, but not necessarily those of the organization they are associated with, including the NYS Task Force on Life and the Law.

DNR Orders

A DNR Order is an order written by a physician that directs staff not to attempt to resuscitate a patient in the event the patient has a cardiac arrest—that is, the patient's heartbeat and breathing stops. Resuscitative measures could range from very basic techniques like basic life support (BLS)[6] to advanced technological interventions such as intubation and even the use of more advanced techniques such as ECMO (extracorporeal membrane oxygenation) which is much like a heart-lung bypass machine used during heart surgery.[7] The range of resuscitative options hinge on where the event occurs, and available resources and personnel.

In general, a DNR order is considered when a patient is at high risk of dying, resuscitative efforts would neither alter the outcome nor address underlying disease processes that placed the patient at risk of dying, and such efforts would interfere with a more peaceful death.

New York's Former DNR Law (1988-2010)

New York's former DNR Law, which went into effect in 1988, was based on recommendations by the NYS Task Force on Life and the Law. Governor Mario M. Cuomo and Health Commissioner David Axelrod had asked the Task Force to study DNR orders in the wake of media reports about legally and ethically questionable practices at several hospitals, such as covert DNR orders, slow codes and show codes.[8] The Task Force's position was that a DNR order is ethical and should be lawful if:

(1) the patient has capacity and consents to the order, or

(2) the patient lacks capacity, meets certain clinical criteria, and an appropriate surrogate decision-maker

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(if there is one) consents to the order based on the patient's wishes if reasonably known, or else best interests.[9]

The resulting DNR Law reflected those principles. With respect to the clinical criteria, under the DNR law a surrogate decision-maker could consent to the entry of a DNR order for a patient who lacked capacity if physicians found that the patient met any one of the following four clinical criteria:

- the patient has a terminal condition;
- the patient is permanently unconscious;
- resuscitation would be medically futile; or
- resuscitation would impose an extraordinary burden on the patient in light of the patient`s medical condition and the expected outcome of resuscitation for the patient.[10]

Moreover, for a patient who did not have a surrogate, a DNR order could be entered if two physicians found to a reasonable degree of medical certainty that "resuscitation would be medically futile."[11]

The statute defined "medically futile" to mean

> that cardiopulmonary resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs.[12]

This provision was intended to limit this discretionary authority to examples of what has been described in the medical ethics literature as "physiological futility,"[13] in which it is not possible to either provide treatment or that treatment to a reasonable degree of medical certainty would not be successful. An example of the former might be a mass in the trachea that precludes the ability to place a breathing tube necessary for ventilation. An alternate scenario might be a refractory chemical abnormality called acidosis which makes it difficult to treat malignant cardiac arrhythmias.[14] Under these circumstances continued resuscitative efforts would be futile. Indeed, the principle of futility is invoked at the *end* of every failed cardiac resuscitation when the attending physician decides to stop her efforts to revive the patient. At that juncture she knows retrospectively that her efforts have been, and will continue to be, futile.[15]

The DNR Law was controversial for a range of reasons.[16] But there do not appear to have been concerns about the statutory definition of medical futility or the ability to recognize medical futility in clinical practice.[17] Indeed, for over two decades it was part of New York's clinical landscape and a useful means to provide competent and compassionate care at life's end. As such, we urge its reincorporation into New York law.

The Family Health Care Decisions Act (2010)

The former DNR Law addressed only one specific end-of-life decision: the withholding of cardio-pulmonary resuscitation. There remained a compelling need to authorize surrogate decisions for the withdrawal or withholding of other life-sustaining treatments such as a ventilator, feeding tube, dialysis, and life-sustaining medications or surgeries. As important, there was a need to override New York's stringent "clear and convincing evidence" rule for such decisions,[18] which restricted family decision-making at the end of life.

In 1992, the Task Force authored a report "When Others Must Choose" recommending a more general surrogate decision-making law that closely followed the DNR Law framework.[19] It advised that surrogate consent to the withdrawal or withholding of life-sustaining treatment from a patient who lacks capacity is ethical and should be lawful if the patient meets certain clinical criteria, and an appropriate surrogate decision-maker (if there is one) consents to the order based on the patient's wishes if reasonably known. If they were not known, a decision could be based upon a best interests.

In 2010, 18 years after the Task Force issued its report, the New York State Legislature passed the Family Health Care Decisions Act (FHCDA).[20] The statute is closely based on the Task Force recommendations.[21]

Surrogate Consent to a DNR Order Under the FHCDA

The passage of the FHCDA repealed New York's former DNR Law with respect to DNR orders in hospitals and nursing homes, and made such decisions subject to FHCDA's more general standards for the withholding and withdrawing of life-sustaining treatment.[22] The rationale was that there was no longer a need for a separate surrogate decision-making law for DNR decisions; that DNR decisions could be subject to the same clinical criteria that apply to other surrogate decisions to forgo life-sustaining treatment. The FHCDA criteria for surrogate consent to a DNR order are as follows:[23]

> (i) Treatment would be an extraordinary burden to the patient and an attending physician determines, with the independent concurrence of another physician, that, to a reasonable degree of medical certainty and in accord with accepted medical standards,
>
> (A) the patient has an illness or injury which can be expected to cause death within six months, whether or not treatment is provided; or
>
> (B) the patient is permanently unconscious;[24] or

(ii) The provision of treatment would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances and the patient has an irreversible or incurable condition, as determined by an attending physician with the independent concurrence of another physician to a reasonable degree of medical certainty and in accord with accepted medical standards.

Notably, the FHCDA criteria does not explicitly list medical futility as a basis for a DNR order.[25] Arguably every case that would have met the former DNR Law's medical futility standard will meet the current FHCDA "inhumane or extraordinarily burdensome" standard. But that standard is more about a proportionality versus a futility assessment. Under the FHCDA the calculus is the relationship of burdens to benefits in which decisions to forgo life-sustaining therapy can be made when ongoing treatment is so disproportionate as to constitute a burden. But in practice, the standard is problematic for clinicians to apply. The determination that resuscitation would be "inhumane and extraordinarily burdensome" under the circumstances involves more of a qualitative, subjective, value judgment than the more quantitative, objective, medical prognosis that CPR "will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs."

Consider the case described at the outset of this article. Under the former DNR Law, the attending physician and a concurring physician could confidently state that if Ms. D's condition declined to the point where her heart stopped, resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs. Indeed this case is a classic and common situation in which a DNR order would be advisable and appropriate.

The FHCDA criteria is more difficult to apply to this case. An attending and concurring physician could feel less confident about stating—indeed less qualified to state—that CPR "would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances," especially because patients become unconscious when resuscitation is performed. The burden is often more for those who witness or participate in the resuscitative efforts.

Moreover, the physicians might be hesitant to declare that "the patient has an irreversible or incurable condition." It is true that her dementia cannot be treated and is progressive and terminal, but her cardiac arrest could be a function of her pneumonia which might be reversible. Despite these interpretive issues raised by the provisions of the FHCDA, the ethical and clinical appropriateness of a DNR order in this case is as strong now as it was when the former DNR Law was in effect.

To be sure, many—perhaps most—physicians will conclude that the case described meets the "inhumane or extraordinarily burdensome" test and the "irreversible or incurable condition" test. Moreover in many cases, the DNR order can be supported by a finding that the patient is "expected to die within six months."

Even so, the removal of the DNR medical futility standard has diminished the clarity of the clinical standard and created a likelihood of greater variability in physician determinations of DNR eligibility in clinically similar cases.

"[T]he FHCDA, by attempting to create clinical criteria that could apply to all end-of-life decisions, forfeited the helpful specificity of the prior medical futility standard for DNR decisions."

Put differently, the FHCDA, by attempting to create clinical criteria that could apply to all end-of-life decisions, forfeited the helpful specificity of the prior medical futility standard for DNR decisions.

The futility standard had important merit beyond just clarity: it had the effect of reducing the emotional burden on the conflicted surrogate who felt that they could not let go. Once a physician notifies the surrogate that resuscitation would be medically futile, the difficulty of this decision is lessened. The surrogate is apt to feel that their consent to the DNR order is not so much their personal choice as much as a recognition of the medical circumstances and the futility of attempting resuscitation. Reinserting the futility provision would allow a clinician to suggest that resuscitation not be attempted because she views its provision as futile, and seek a surrogate's acknowledgment rather than having to pose the choice as more neutral question. In our view, by providing this guidance to surrogates about what is in the realm of the medically possible, clinicians can better lead families through the challenges of decisions at life's end.

DNR Orders for Patients Without Surrogates

A similar, and perhaps greater, problem relates to decisions for patients who do not have a surrogate. Under the former DNR Law, when a patient lacked capacity and did not have a surrogate, a DNR order could be entered only if

the physician and a concurring physician determined that resuscitation would be medically futile.[26] Here again, the FHCDA eliminated that DNR-specific standard in favor of a more general standard for the withdrawal or withholding of any life-sustaining treatment. The standard is very restrictive: treatment can be withheld (and therefore a DNR order can be issued) if the attending physician and another physician determine to a reasonable degree of medical certainty that:

(i) life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and

(ii) the provision of life-sustaining treatment would violate accepted medical standards...[27]

The imminently dying standard resembles the "medical futility" standard, but is problematic as applied to the DNR decision. When a DNR order was based on medical futility, the physicians were saying "*if and when in the future this patient's heart stops*, it will not be possible to start it again, or start it for very long." But the medical futility standard did not ask the physicians to predict when that cardiac arrest could occur; indeed, it might not occur for a very long time and prognostication at the end of life can be very difficult.[28]

In contrast, some physician might read the FHCDA standard as requiring physicians to determine that the patient is *imminently dying at the time they are writing the DNR order*. If so, that would be far more restrictive than the former DNR Law's medical futility standard was and limit decisions to withhold or withdraw care to patients clearly in extremis. That reading would exclude patients who if they were to have a cardiac arrest would not likely have a successful resuscitation.

To be sure, the FHCDA standard does not have to be read that narrowly. It should be read to mean, as applied to a DNR decision, that doctors must find that the patient will die imminently *if and when the patient has a cardiac arrest*—which is the moment that the treatment will be withheld. A Q&A on the New York State Bar Association's FHCDA Information Center takes this position.[29]

But the fact is, the clause is ambiguous, and capable of two interpretations. Some clinicians tend to read it in a conservative manner, perhaps making the reach of the law more narrow than what was envisioned by legislative intent. It therefore creates a risk of variability in physician determinations in clinically similar cases. Restoring the medical futility standard would enhance consistency, and reduce concern about an excessively narrow application of the "imminent dying" test.

If we reconsider the case of Ms. D., but now assume she has no close family or friends, the challenge of this provision becomes clear. Under the former DNR Law the attending with a concurring physician could have a written a DNR order based on the finding that CPR would not work. Under the FHCDA standard, the attending would struggle over two more complicated questions: (i) whether the patient will die imminently (and whether that refers to at the time the order is written or at the time of a future cardiac arrest); and (ii) whether CPR would violate accepted medical standards. Here again, these more general standards would likely result in variability in determinations in like clinical cases—with no rationale for the variability other than difficulties applying the standard.

Legislative Proposal

The problems noted above can easily be remedied as a drafting matter: The FHCDA should be amended to restore medical futility as one of the bases for writing a DNR order when either a surrogate consents to the DNR order or when a patient does not have a surrogate. This can be done while leaving in place the existing criteria as other bases to write a DNR order.

Legislative bills have been introduced in the Legislature since 2011 that would accomplish such amendment.[30] Unfortunately a bill has not yet passed in either the state Assembly or Senate. We urge that this be done.

Legislators are understandably wary about any bill that addresses the topics of DNR and medical futility. But in this instance, they can be reassured: the bill does not introduce a new untested standard; it simply restores the standard that was in effect and worked well for 23 years. And the bill does not authorize a physician to write a futility DNR order unilaterally when there is a surrogate; if there is a surrogate, that surrogate's consent is required for the DNR order.

Instead, the bill will help improve end-of-life decisions by clarifying that a physician can write a DNR order for a patient who lacks capacity, among other circumstances, when the attending physician finds that resuscitation would be "medically futile," another physician concurs, and a surrogate decision-maker consents to the DNR order. And if the patient has no surrogate, an attending physician, with the concurrence of another physician, could write the order based on medical futility in the absence of a surrogate.

Other Issues

A bill to restore the medical futility will not resolve all the issues relating to the entry of DNR orders, some of which are long-standing and some recent. For example:

Do Not Resuscitate vs. Do Not Intubate. The confusion between DNR and DNI persists. It is our view that an order not to intubate must always be accompanied by a DNR order, as intubation is a key component of resuscitation. Conversely, patients can be intubated and still be DNR, when intubation is elective and not in the setting of a cardiac arrest.

Diagnosing Permanent Unconsciousness. Recent data suggests that upwards of 41% of patients thought to be permanently unconscious in the permanent vegetative

state are in fact in the minimally conscious state (MCS). We urge the Department of Health to issue clinical guidelines to assess and diagnose disorders of consciousness, much as it did for the determination of brain death.[31]

DNR Suspension During Surgery. We would like to see DOH guidance or regulations, such as those that existed when the former DNR Law was in place, stating that DNR orders cannot be unilaterally suspended during surgery without the patient's or surrogate's consent and that the reversal of DNR status could not be a precondition for surgery, which is often palliative under these circumstances.[32] This is the "required reconsideration" standard adopted by the American College of Surgeons.[33]

New Resuscitative Technologies. Reinstating provisions of the former DNR Law would not address its appropriateness and applicability to new resuscitative technologies. We think some of these issues are ripe for review by the Task Force with input from professionals and the public.

But the perfect should not be the enemy of the good. There is much to be done to update our laws about end-of-life care in New York. But short of those more ambitious goals, the Legislature can act promptly to make what should be a noncontroversial, simple improvement to the FHCDA: restore the former medical futility standard as one of the bases for a DNR Order.

Endnotes

1. NY Public Health Law (PHL) Article 29-B, added by NY Laws of 1987, chapter 818, eff. April 1 1988. *See also* the Department of Health's nearly identical hospital regulations. 10 NYCRR § 405.43 (repealed March 11, 2014).
2. PHL § 2965.3(c).
3. Id., § 2966.1
4. PHL Article 29-CC, added by NY Laws of 2010, chapter 8.
5. PHL § 2994-d.5.
6. E.g., manual chest compression with the mouth-to-mouth supply of oxygen.
7. This is not a description of the standard of care, but a description of the range of technological interventions that might be used in a resuscitation effort.
8. See *Law Proposed for Withholding Emergency Care*, NY Times, April 20, 1986, p. 38.
9. NYS Task Force on Life and the Law, *Do-Not-Resuscitate Orders* (1986).
10. Former DNR Law § 2965.3(c).
11. PHL § 2966.1(a).
12. PHL § 2961.12.
13. See S.J. Youngner, M.D., *Who Defines Futility?*, J. American Medical Assn Oct. 14, 1988 2094-5.
14. See NYS Task Force on Life and the Law, When Others Must Choose (March 1992) p. 196.
15. J.J. Fins, *A Palliative Ethic of Care: Clinical Wisdom at Life's End* (Sudbury MA: Jones and Bartlett Publishers, 2006).
16. See e.g., R. Baker and M. Strosberg, *Legislating Medical Ethics: A Study of the NY Do-Not-Resuscitate Law* (Springer 1995).
17. However, there was considerable debate about the need for surrogate consent in instances where physicians determined that resuscitation would be medically futile. That is not the topic of this article. See Youngner, note 12 above.
18. See R. Swidler, *Harsh State Rule on End of Life Care Remains in Need of Reform,* N.Y.L.J., Jan 26, 2000, p. 1.
19. NYS Task Force on Life and the Law, *When Others Must Choose* (1992).
20. Ch. 8, L. 2010.
21. See R. Swidler, *The Family Health Care Decisions Act: The Legal and Political Background, Key Provisions and Emerging Issues*, N.Y. St. B.J. (June 2010), p. 18.
22. To be precise, Ch. 8, L. 2010 amended the former DNR Law, PHL Article 29-B, to make it applicable only in psychiatric hospitals, psychiatric units, and developmental centers—locations that the FHCDA did not reach.
23. PHL § 2994.d.5. The criteria for a patient without a surrogate are different, and are discussed further below.
24. We discuss this standard in the final section of this article.
25. NY Public Health Law § 2994-d.5.
26. NY Public Health Law § 2966.1.
27. NY Public Health Law § 2994-g.5.
28. See Nicholas A. Christakis, *Death Foretold: Prophecy and Prognosis in Medical Care* (U. Chicago 1999).
29. See http://www.nysba.org/ FAQ VI.1:

    > VI. Health care decisions for adult patients without surrogates. (PHL §2994-g) (Revised Sept. 21, 2010).
    >
    > 1. Q—Under the former DNR law, a DNR order could be entered for an incapable patient who did not have a surrogate if the physician and a concurring physician determined that resuscitation would be" medically futile" (i.e., if CPR would "be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs"). Can a physician still do that?
    >
    > A—The language of the standard has changed, but it still ordinarily supports the entry of a DNR order if resuscitation would be "medically futile" as defined above. Under the FHCDA, the physician and a concurring physician would need to determine that (i) attempted resuscitation (in the event of arrest) would offer the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the attempt would violate accepted medical standards.
30. E.g., A.3991 (Gottfried)(2017); S.4796 (Hannon)/A.6966 (Gottfried) (2015).
31. See Schnakers C, Vanhaudenhuyse A, Giacino J, Ventura M, Boly M, Majerus S, Moonen G, Laureys S., *Diagnostic Accuracy of the Vegetative and Minimally Conscious State: Clinical Consensus Versus Standardized Neurobehavioral Assessment*, BMC Neurology, 2009, 9:35. More generally see Fins JJ., Rights Come to Mind: Brain Injury, Ethics and the Struggle for Consciousness (New York: Cambridge University Press, 2015).
32. See *NYS DOH Health Facilities Memo* H-27; Rhcf-22; Hha-19; Hospice-10, Subject: DNR Law Changes (11/2/1992) at p. 14-5.
33. See www.facs.org/about-acs/statements/19-advance-directives.

The Disconnect Between Judicial Approaches to Nursing Home Arbitration Clauses and Malpractice Waivers

By Evan Lehrer

I. INTRODUCTION

Contracts are an exercise of autonomy, and in general people are free to bargain and be held to their bargain. But in areas such as nursing home arbitration agreements and malpractice waivers, courts and policymakers have struggled to balance the principle of contractual autonomy and the public policy interest in protecting residents and patients. First, this article will provide background information on how courts approach issues of consent regarding arbitration clauses in nursing home agreements and then on how they approach waivers of medical malpractice.[1, 2] Afterwards, Part III will address potential reasons for the judicial disconnect including the Federal Arbitration Act, if arbitration rises to the same level of concern as malpractice waivers, and whether arbitration provides a net benefit to society. Originally, this article was to provide a potential solution, promoting transparency and market forces, to protect consumers from overly broad contracts. However, recent federal regulation has outright banned pre-dispute arbitration in nursing home admissions; last than a month later the legality of the regulation has already been challenged.

II. CONTRACTS IN THE HEALTH ARENA

A. Arbitration Clauses in Nursing Home Agreements

Moving a loved one to a nursing home is a somber thought. The process of moving a family member to a nursing home is often a time of vulnerability, as family members deal with the emotional aspects of relocating a loved one from their residence to a nursing home. This relocation also involves harsh financial realities: the nationwide average daily rate in a nursing home is $250 for a private room and $220 for a semiprivate room, which equals $91,250 and $80,300 per year respectively.[3] During this process, individuals will sign a contract with the nursing facility. Parties often use the language of contracts to provide a final statement of the risks and obligations each party bears, including the mechanisms for post-agreement disputes. Increasingly nursing home agreements include an arbitration clause.

The process of arbitration can be likened to the popular daytime show Judge Judy:[4] the parties mutually agree to take the dispute to a non-judicial imperator whose decision is honored as if it came from a judicial body. Prospective nursing home residents sign such arbitration clauses that often include a waiver to their right to a jury trial, an allocation of fees for the cost of arbitration, limitations on discovering evidence, curtailments on their right to appeal, and a covenant to keep the resolution confidential.[5] Additionally, as a matter of case law (rather than contractual law) the courts are restricted in their ability to review an appeal arising from arbitration.[6] Unlike the relatively comedic matters that go in front of Judge Judy, arbitration may encompass any dispute that arises between the parties.

For example, a son was required to arbitrate his wrongful death claims when his 100-year-old mother, a nursing home resident, was strangled to death by her roommate.[7] The son alleged that the nursing home had notice that the roommate was dangerous due to several of her past actions. Prior to the arbitration hearing, the son's legal team discovered that the arbitration firm managing the hearing had previously handled more than 400 arbitrations for the law firm representing the nursing home company, an indication the arbitration firm may be more favorable to the company giving them business (per their contracts). The arbitrator ultimately ruled in the nursing home's favor but provided no explanation.[8] Indeed, the arbitrator had no obligation to publicly report its decision or base its decision on precedent, unlike that of the judicial system.[9] However, the nursing home resident apparently agreed to this arbitration process when she signed the contract.

When people are presented with a complicated contract that they do not understand, they are advised to consult a lawyer. Given the emotional and time constraints faced by families of prospective nursing home residents, however, such advice may not be practical. While some families have a time to search and inquire about nursing homes in their area, others must make a choice very quickly. When a vulnerable person is being discharged from the hospital, there is intense pressure to find a nursing home quickly.[10] Hospital policies typically require that patients with significant continuing nursing needs be discharged to nursing home settings soon after surgery and/or after critical stages of their care.[11] The need to find a long-term care placement arises quickly and often is unplanned, such as in response to the death of a caregiver or spouse, leaving little time to investigate options or to wait for an opening at a facility of one's choice.[12] Under the time pressure of the pending discharge, patients and families cannot be expected to negotiate or haggle over legal/technical nursing home contract language—even if they can identify and understand the full ramifications of a mandatory arbitration clause. It cannot reasonably be argued such individuals have the opportunity to investigate and visit other nursing homes before making a carefully considered "choice."[13]

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As this article will show, arbitrations clauses in nursing home agreements, unlike medical malpractice waivers, have been largely upheld by the courts when challenged.[14] In the absence of judicial scrutiny on the use arbitration agreements by nursing homes, other stakeholders have spoken out against them. For example, the American Bar Association passed a resolution opposing pre-dispute arbitration agreements between long-term care facilities and residents, going as far as to reject the voluntariness of any "voluntary arbitration."[15] Several recent Congressional bills were aimed at curtailing, eliminating or streamlining arbitration clauses in nursing home contracts.[16] As Senator Al Franken stated:

> All too often, only after a resident has suffered an injury or death, do families truly understand the impact of the arbitration agreement they have already signed...we strongly urge CMS [Center for Medicare and Medicaid Services] to fully protect residents and their families by banning pre-dispute arbitration clauses in long-term care facility contracts.[17]

This quote is problematic from a contract law perspective. A party's failure to read or understand a contract, which they signed, is not a legal basis for revoking a contract.[18, 19] Only under certain circumstances, such as when a contract is unconscionable to be outrageously unfair or when an individual is under "undue influence" from another party, can a person legally back out of a contract.[20] Specifically for contracts of adhesion, standard forms prepared by one party that involve little to no bargaining and presented as either-take-it-or-leave-it,[21] courts often invalidate the contractual language if a reasonable person would have not expected that legal obligation.[22] Plaintiffs invoke arguments of unconscionability, contract of adhesion issues or undue influence against arbitration clauses with nursing homes, but these arguments rarely succeed.

Before addressing unconscionability, contracts of adhesion issues or undue influence arguments, courts often address defenses regarding the prospective resident's mental capacity to consent. Defendants, the nursing home, frequently respond to claims of capacity by asserting that the resident has never been declared legally incompetent and, therefore, had sufficient mental capacity to contract regardless of whether the resident suffered from any mental deficits. The law in many states supports this argument, providing that a party is presumed sane, fully competent and capable of understanding the nature and effect of his or her contracts.[23] Often the party seeking to invalidate a contract on grounds of mental incompetence bears the burden of proving the alleged incompetence. Because the courts start their line here, their further analysis, if any, for signs of unconscionability, unreasonable expectation in a contract of adhesion or consent given under undue influence is an uphill battle, as the court has already declared them to be mentally competent to sign a contract.

1. Unconscionability

One potential ground for barring the enforcement of a contract is that the provision is unconscionable. Many jurisdictions require a plaintiff to prove both "procedural" and "substantive" unconscionability to establish the defense of unconscionability.[24] In analyzing procedural unconscionability, courts emphasize several factors: (1) whether the plaintiff had "meaningful choice" in deciding on a nursing home, (2) the arbitration clause's legibility for a layperson and (3) whether the plaintiff had a chance to rescind the contract after signing. Regarding substantive unconscionability, courts generally look to whether the terms of the agreement are "outrageously unfair."[25] The burden rests on the plaintiff to show these factors. In addressing these factors, courts have been very generous in finding favorable factors for the nursing homes.

a. Procedural Unconscionability and Meaningful Choice

A court looks at the circumstances surrounding the transaction to determine whether the complaining party had a "meaningful choice" at the time the contract was entered, including alternative options in the geographical area. For example, two nursing homes in the county were enough for a person to have a "meaningful choice" in deciding the nursing home.[26] An appeals court in Ohio, found there was a lack of meaningful alternatives because of the difficulty of finding quality nursing homes. On appeal, the Supreme Court of Ohio overturned, saying there was no sufficient evidence in the record to suggest there was a lack of quality nursing homes in Ohio.[27] A Pennsylvania court even went as far as presuming there were similarly priced nursing homes in the area to determine the plaintiff had meaningful choice when finding a nursing home.[28]

Plaintiffs have more favorable odds in the courts that have interpreted the "meaningful choice" prong to mean that a party lacked a meaningful opportunity to decline that provision.[29] For example, in *Raiteri v. NHC Healthcare/ Knoxville, Inc.*, the Tennessee Court of Appeals noted that the husband, signing for his wife's admission to the nursing home, was visibly distraught and confused.[30] The nursing home representative said that she would explain the contract to the husband but never explained the arbitration provision. The court concluded that the husband lacked realistic choice on whether to accept the contract or not because the contract was confusing and the nursing home knew he was going through an emotionally difficult time. This interpretation is very similar to contracts of adhesion, whether the provision was declinable for purposes of admission/services, so it will be covered in more detail later. But as we shall see, unlike *Raiteri,* courts are very reluctant to impose a duty for a nursing home to explain the contract, especially when the arbitration

provision was displayed conspicuously. *Raiteri* may be an outlier because the court took particular note that the nursing home representative assured the husband that she would explain the contract, but then provided for no explanation for the arbitration provision. Rarely do nursing homes take on the additional burden of giving a verbal guarantee that they will explain the contract.[31]

b. Procedural Unconscionability: Arbitration Displayed Conspicuously

Courts have repeatedly determined there was a lack of procedural unconscionability, even if the nursing home did not explain the provision, so long as the provision was displayed conspicuously. Signs that the provision was displayed conspicuously include: the length of the provision, the language used in the provision and whether the typeface was the same as the rest of contract or whether the typeface was bolded. An arbitration clause was enforceable when appearing on the last page of a six-page agreement, in all caps and bolded.[32] In a separate case when an arbitration provision was located on pages 12 and 13 of a contract, use of boldfaced and underlined words to highlight descriptive phrases like "Resolution of Disputes" was enforceable.[33] In contrast, when the arbitration clause was buried within a 37-page document, procedural unconscionability was found.[34] This analysis overlooks that parties do not read contracts, as contract law steadfastly seeks to bestow an obligation on parties to read the contract before they sign.

Should the nursing home take these steps to make the arbitration clause conspicuous, courts are extremely reluctant to impose a duty on the nursing home to explain the contract. It was unnecessary for the nursing home to explain the arbitration provision containing a jury waiver to an elderly woman, when the arbitration clause was in a separate document, because the language was in bold and was stated as not a precondition for admission.[35] Even when arbitration was a precondition for admission, failing to question or show confusion over the clause naming American Health Care Lawyers Association as the arbitration body demonstrated the plaintiff accepted the appointment at time of signing.[36] Arguments that no one explained the arbitration provision including waiver the right to a jury trial, that the burden of proof would be higher in arbitration than in court and a change in the structure of awarding attorney's fees were all "insufficient, as a matter of law," to support a finding of procedural unconscionability.[37] One case went as far that in the event of a photocopying error that omitted portions of the arbitration clause, it was the plaintiff's responsibility to ask for the missing provisions before signing.[38] Then when the contracts provide an opportunity to rescind, courts are less likely to disturb the contract because the nursing home resident had extra opportunity to read the contract.

c. Procedural Unconscionability: Opportunity to Rescind

Courts generally respond favorably when the arbitration clause provided for an opportunity to rescind consent. Several cases found that rescission provisions, where the resident or his or her estate could rescind consent on the arbitration clause within a 30-day window after signing, was a factor against unconscionability.[39] One case, held arbitration was enforceable when the rescission provision was only exercisable within a three-day window.[40] In that case, the court expected the prospective resident to consult with an attorney within the three-day window if they did not understand the provision.[41] A Tennessee court, while sympathetic to the plaintiff's fear that if he invoked the 10-day recession clause then his mother would be discharged from the facility, still upheld the arbitration provision because it felt that it was no more problematic than terminating a doctor-patient relationship.[42] If the party failed to show procedural unconscionability, then it failed to demonstrate unconscionability as a whole and would be bound to the contract it signed.

d. Substantive Unconscionability: A Sound Bargaining Position

After demonstrating procedural unconscionability, that party must then show substantive unconscionability. Substantive unconscionability is often described as the doctrine against unfair surprises.[43] Mere inequality of bargaining power is insufficient to show unconscionability.[44] Instead, courts analyze whether a person was in an objectively sound bargaining position and could take note of any "outrageously unfair" terms. A sound bargaining position takes in to account the person's education level and/or business acumen. An elderly woman whose "ailments…undoubtedly genuine and painful" and with a "poor memory" was "not sufficient" to find the agreement unconscionable.[45] The Supreme Court of Ohio, when overturning the appeal's court finding of an unenforceable contract, suggested the appellate court overrelied on the woman's age, 95, in finding the contract to be unenforceable: "Our citizens do not lose their constitutional rights [freedom to contract] and liberties simply because they age."[46]

When a son or daughter signs the contract for the prospective resident, the courts often look at that individual's education and business acumen instead. An individual who graduated high school, but not college, and worked at a factory for 15 years was deemed to be a person who was found to be in a sound bargaining position.[47] Simply trying to admit an ailing parent to a nursing home, while leaving the plaintiff in a vulnerable position, did not rise to unconscionability.[48] By contrast, in Florida a husband with no legal education was enough to show that he did not understand what rights he was signing away in the arbitration agreement.[49]

In comparison to these cases, the West Virginia Supreme Court has a history of approaching arbitration clauses in nursing home agreements with skepticism. Originally, the West Virginia Supreme Court held that arbitration clauses in nursing home agreements were categorically unconscionable. By so ruling, West Virginia was potentially in conflict with a federal statute that favored arbitration, the Federal Arbitration Act[50] (which will be discussed in greater detail later in the article). West Virginia concluded that Congress did not envision wrongful death claims to be arbitrated, therefore nursing home arbitration did not benefit from the federal statutory protection. The United States Supreme Court, in a per curiam opinion, disagreed with the interpretation.[51] Although the West Virginia Supreme Court complied with the U.S. Supreme Court's order, it did not refrain from criticizing arbitration agreements in nursing home contracts, noting that these contracts were frequently signed "in a tense and bewildering setting." West Virginia is still concerned with the use of arbitration in cases of nursing home negligence, and remains resolute that unconscionability can be appropriately invoked to invalidate arbitration agreements (albeit not a categorical ban).[52]

2. Contract of Adhesion

> A contract on a printed standardized form that is offered on a take-it or leave-it basis—usually by a merchant that monopolizes a particular market, or whose bargaining power significantly outweighs that of the consumer—is a contract of adhesion. Such a contract exists where a party of superior bargaining strength, *i.e.*, a vendor, provides a subscribing party only with the opportunity to adhere to the contract or forfeit use, ownership or access to the vendor's services and goods.[53]

When a court is asked to scrutinize a contract of adhesion, the court looks for terms that were either "unreasonable" or "reasonably unexpected." Many people fail to read a contract of adhesion, such as the "Terms of Use" for iTunes or the conditions for a credit card.[54] Courts impose the reasonable expectation analysis to invalidate language that a reasonable consumer would not expect. Concerns over contracts of adhesion are often invoked in discussions of unconscionability, as both doctrines are invoked to avoid unfair surprises.[55]

As discussed in the unconscionability section, some nursing homes present the arbitration clause in a separate document and expressly mark it as not a precondition for admission.[56] So long as the contract, including the arbitration clause, is not a precondition for admission, the contract does not constitute a contract of adhesion.[57] To qualify as a contract of adhesion, the signature needs to be a prerequisite of obtaining the goods or services.

Nevertheless, there are still some cases where the arbitration clause is a condition of admission. In a wrongful death case, the estate sought to invalidate an arbitration clause that included a jury waiver. The court dismissed the estate's claim, holding that such waivers were quintessential features of arbitration and could be expected in a contract of adhesion.[58] One court said that arbitration clauses are so prominent in nursing home agreements that the very presence of one can be expected.[59] In contrast, an arbitration clause providing a limitation on punitive damages, on up to $50,000, was unreasonable and was struck down by a court.[60]

As the author was reviewing the jurisprudence on this issue, he kept coming across a rare sight: judges opining a hypothetical. As the burden of evidence is on the party wishing to break from the contract, courts are willing to infer in the absence of evidence that the arbitration clause was negotiable.[61]

- "More particularly, there is nothing to suggest that, had Ms. West [the plaintiff] so requested, the arbitration provision would not have been deleted."[62]
- "There was no evidence that the mother would have been denied admission to the facility if the daughter had declined the arbitration agreement."[63]
- "Furthermore, Appellant could have asserted her power as a paying customer and demanded removal of the arbitration provision in exchange for her business."[64]

Outside of submitting alternative contracts where the arbitration provision was omitted per a negotiation, the author finds it difficult to imagine how courts can be so certain that the arbitration provision was negotiable. Actually, in one of the few cases the author found where the court deemed the contract to be overly adhesive, the plaintiff showed evidence that no other resident ever made changes to the nursing home's admission agreement.[65] A study of nursing homes in North Carolina indicated that some facilities treat the arbitration agreement as a condition for admission despite language saying the agreement was voluntary.[66] The judicial disconnect on what prospective nursing home residents encounter when contracting with nursing homes has created an uphill battle for plaintiffs trying to demonstrate grounds for backing out of a contract.

3. Undue Influence

Generally, unconscionability is the favored argument advanced by plaintiff counsel. As a result, there are few cases that address undue influence. A majority of cases provide a brief mention of undue influence, but proceed with an unconscionability analysis.[67] Undue influence, as defined by the Second Restatement of Contracts, is "un-

fair persuasion of a party who is under the domination of the person exercising the persuasion or who by virtue of the relation between them is justified in assuming that that person will not act in a manner inconsistent with his welfare."[68] Contracts are often scrutinized for signs of undue influence when the parties shared a fiduciary relationship. A fiduciary duty is when one party has an obligation to act in the other party's best interest.

Fiduciary duties may be identified through statutes, contractual duties or common law. Relationships involving high levels of trust often involve a fiduciary relationship.[69] Some common examples of fiduciary relationships are those between lawyers and their clients; Board of Directors and the corporation (often the shareholders); and physicians and their patients.[70] Some courts impose as a matter of common law a fiduciary duty between nursing homes and their residents, other courts do not.[71]

Several decades ago, New York courts recognized that many similarities between a patient and doctor also exist in the nursing home context. Therefore, the court extended a fiduciary duty, as a matter of common law, to the nursing homes and their residents:

> It is indisputable that…there existed between the donor and donee a fiduciary Relationship arising from the nursing home's assumption of complete control, care and responsibility to and for its resident…The acceptance of such responsibility with respect to the aged and infirm…resulted in the creation of a fiduciary relationship….[72]

In contrast, West Virginia in *Manor Care, Inc. v. Douglas*, in a case of first impression on whether a fiduciary duty exists between a resident and their nursing home, was asked to uphold the trial jury's finding that there was a breach of fiduciary duty and the respective compensatory damages.[73] Despite recognizing that a number of jurisdictions have established such a duty of fiduciary responsibility, *Manor Care* declined to recognize a fiduciary relationship, fearing "a reasonable inference could be made that each and every employee of the [nursing home], from the janitorial staff…owed a fiduciary duty to the Plaintiff."[74]

A court may harbor concern that finding a fiduciary duty in this area will lead to uncontrollable burden but still invoke undue influence; while a fiduciary duty is often sufficient to invoke undue influence, it is not necessary to invoke undue influence. There exists instances where no fiduciary duty is present but undue influence is still invoked, such as in contexts between a religious patron and a parishioner.[75] In these contexts the relationship is still one with a special level of confidence.[76] One factor that courts recognize as showing a level of undue influence was exerted on the religious patron is their age and their physical or mental dexterity.[77] Therefore, a court's reluctance to impose undue influence in this area cannot solely be justified over concerns of *runaway* fiduciary duty liability.

In *Hollingshead v. A.G. Edwards & Sons, Inc.*, one of the few cases to conduct an undue influence analysis, the lower court denied the nursing home's motion to compel arbitration, finding the plaintiff factually argued undue influence.[78] The *Hollinshead* Court was very hostile towards the undue influence argument, noting that undue influence was never previously invoked in the context of nursing home agreements.[79] Additionally, the appellate court categorized the relationship between the prospective resident and the nursing home as simply a transactional relationship and did not rise to the level of finding fiduciary duty to conduct an undue influence analysis.[80] *Hollingshead* continued to find that even if the nursing home had exerted undue influence, there was no evidence that the prospective resident was unduly influenced. The treatment of undue influence as a novel argument is another demonstration that the judges are disconnected from the harsh realities of nursing home agreements.

The repeated failure to reject arbitration clauses in nursing home agreements on grounds of unconscionability or undue influence forced attorneys to reevaluate their strategies. Instead, attorneys find judges are more receptive to arguments that whoever signed their contract lacked power of attorney.[81] If person A gives Person B power of attorney, then B can contractually bind A to an obligation or agreement, for example, a son/daughter contractually binding a parent to a nursing home contract. Some states have statutes that permit nursing homes to reasonably imply a person has power of attorney for a family member; in other states the delegation must be express.[82] Invalidating a contract for lack of power comes with a more technical standard than the subjectivity of weighing various factors for signs of unconscionability or unreasonable terms. From the repeated reluctance to find contracts unconscionable, the willingness of courts to opine that prospective residents are in bargaining positions and *Hollingshead,* there is a judicial disconnect on how judges view prospective residents for nursing homes versus patients about to sign waivers of medical malpractice.

In contrast to arbitration and nursing homes, an area where judges often invoke and find in favor of arguments on unconscionability, undue influence or against public policy is on medical malpractice waivers. Like admitting a loved one in to a nursing home, the signing of a medical malpractice waiver is done under emotionally-draining circumstances. After providing background information on medical malpractice waivers, this article will identify an apparent disconnect on how judges are willing to approach and scrutinize waivers for medical malpractice. Afterwards, I will explore possible reasons

why judges are reluctant to rearrange consent in arbitration agreements including whether arbitration carries the same concerns as waivers for medical malpractice.

B. Waivers of Medical Liability

Contractual waivers of medical malpractice, often called exculpatory agreements, are an area where courts commonly intervene out of public policy concerns. For example, in New York, the void-for-public-policy rationale was applied against medical malpractice exculpatory agreements in *Ash v. New York University Dental Center*.[83] Interestingly, an earlier New York case invalidated an exculpatory agreement because it did not specifically mention negligence.[84] NYU Dental Center used the same exact exculpatory agreement found in the previous case but simply added a negligence clause to its agreement.[85] The court was forced to confront the enforceability of an exculpatory agreement which it was previously able to avoid on grounds of strict interpretation. Faced with negative case law, where a prior New York Supreme Court case had found a release valid (and was affirmed without opinion),[86] the *Ash* court expressly declined to follow that holding.[87] Instead, the *Ash* court addressed the issue as if it was one of first impression and joined a growing majority of state courts in finding the exculpatory agreement void as a matter of public policy.[88] The court employed a two-pronged test: finding that (1) the "special relationship" between the doctor and the patient, along with (2) the State's interest in the level of care received by its citizens meant that the agreement could not be upheld.[89]

When a court suspects undue influence it may void exculpatory agreements as public policy. In particular, *Ash*'s focus on the "special" relationship between the patient and doctor parallels the concern over undue influence when "domination" is exerted as a "virtue of their relationship." Although the void against public policy rationale of exculpatory agreements is not uniform, it is difficult to find cases where the malpractice waiver was upheld. Critics of cases where the exculpatory agreement was voided accuse judges of employing "hindsight bias." Judges incorrectly focus on the patients (or their estates) once the harm has already occurred rather than the time at which the plaintiff entered into the waiver.[90] If that was the entire case, then judges would be quick to strike down arbitration procedures for wrongful death claims.

Proponents, often economists, for the freedom of contract argue that malpractice waivers should be permissible. First, they argue that by allowing doctors to utilize malpractice waivers then they would not need to take out malpractice insurance and therefore not shift the cost of insurance premiums onto patients. Second, it would permit patients to be able to bargain for a reduced-price surgery in exchange for waiving malpractice.[91]

The first point may be factually inaccurate,[92] but it misses the underlining point of insurance in general: to distribute the costs of malpractice across society. We as society want to promote malpractice insurance because a single malpractice claim can ruin a physician (and under certain vicarious liability circumstances, the hospital or group practice). We as a society want physicians to have malpractice insurance because it guarantees the victim to be, in some way, compensated for their injuries. By having malpractice insurance the cost is spread throughout society so that physicians, wherever they may, can still take patients and help people. Thus, malpractice insurance results in several net benefits for society.[93]

The second point ranges from dubious to incorrect. Leaving aside whether a person would be comfortable bargaining/haggling with their physician over the price of surgery, allowing physicians to waive malpractice liability is unlikely to encourage the "invisible hand of the market" to step in. For example, if medical malpractice waivers were permissible, theoretically there would be two tiers of physicians: physicians who require malpractice waivers but cost less and physicians who do not require it but cost more. What is much more likely to occur is a marketplace where a vast majority of physicians would simply require malpractice waivers. When consumers are left with little meaningful alternatives, most commercial contracts will be identical. For example, this has already occurred in the commercial credit card contracts and arbitration clauses where all the major credit card companies include an arbitration provision.[94] Therefore, invalidating waivers of medical malpractice over concerns that consent was given under coercive and stressful conditions is both pragmatic and justified.

1. However, When Void Against Public Policy Was Applied to Nursing Homes…

Arguments to invalidate arbitration agreements in the nursing home contract as against public policy, like that of malpractice waivers, have failed. The Supreme Court of West Virginia refused to enforce arbitration agreements in nursing home contracts as they were categorically a violation of public policy and unconscionable.[95] However, in a unanimous per curiam opinion, the Supreme Court of the United States held that it was impermissible to invalidate an entire class of arbitration agreements based on state-public-policy grounds as categorically unconscionable.[96, 97] As a direct result, New York and several other states were forced to revisit their state laws that categorically prohibited arbitration clauses in nursing home contracts.[98]

As we have seen, judges have been repeatedly unwilling to scrutinize consent in nursing home cases, although many of the same factors exist in medical malpractice waivers. Part III will explain that judges should approach nursing home cases with greater skepticism and will then explore several possible reasons for the judicial reluctance, including federal statutory protection toward arbitration or a recognition that arbitration provides societal benefits.

III. Connecting the Contracts and the Judicial Disconnect

Before detailing why consent in the contexts of nursing homes and physicians should be seen as analogous situations, I will address whether, as a matter of policy, contract law should even apply to these relationships and maybe not some alternative regime?[99] Contract law largely dominates commercial transactions and the stereotypical theory behind contract law largely presumes that both parties are acting in their self-interest. Despite living in a capitalist society, there are areas, as a matter of federal statutory law, where we shield patients from financial arrangements that may impair a physician's judgment.[100] For example, physicians are prohibited from referring patients for certain health services to another entity if that physician has a financial relationship with the referring entity.[101] A contractual relationship between the physician and the referring entity may implicate a financial relationship, provided it does not meet a federal exception or safe-harbor.[102]

Like the federal statutes policing referrals maybe more protection should be generally imputed in patient-physician relationships. Unlike the profit maximizing of standard contractual arrangements, studies show that individuals do not want an adversarial relationship between themselves and their physician. Instead, patients would like to participate in the decision-making process with their physician. A Canadian study involving 12 different patient populations concluded that:

> Despite consumerist rhetoric among some bioethicists, very few respondents wish an autonomous role. Most wish to share [decision making] with their providers… These results are not what one would expect in a healthcare environment that is strongly influenced by advocates of healthcare consumerism; however they are consistent with a growing body of literature that suggests that a share model of the doctor-patient relationship is desirable. These results help to shed light on what is meant by the "autonomous patient."[103,104]

However, while standard contract theory presumes both parties are acting in their self-interest, it also assumes the finished product will be mutually beneficial for both parties. The idea that a physician's interest is in her paycheck is not mutually exclusive with also seeing her patient recover. Most physicians likely strive to maintain a harmonious balance between their interests and their patients by self-policing themselves with their own rules of professional conduct.[105] Therefore, contract law is neither inherently disharmonious nor undesirable in the health care arena.[106]

A. Connecting Arbitration Clauses and Malpractice Waivers

The law grapples with contracts in the health care arena because they are often used in contexts when one party is in a state of vulnerability. There is literature on how contracts are used as a means of physician control over their patient in the patient-physician relationship.[107] Judges through the doctrines of unconscionability, duress or undue influence seem to be willing to scrutinize the patient's consent to ensure it is actually a manifestation from the patient and not from the physician's control.[108] Particularly in the doctrine of undue influence, these individuals are in vulnerable states, willing to consent to irrational decisions for the chance to get healthy; therefore, there must be indication their consent does not result from the physician's influence. Therefore, as a matter of public policy, we do not honor their consent.[109] However, the discussion thus far has been in the context of physicians. Are concerns of the patient-physician-fiduciary-relationship being exploited to coerce consent also applicable with nursing homes and their residents?

Despite the split in the courts on whether a fiduciary duty is present between nursing homes and their residents,[110] as a pragmatic matter the same concerns in the physician-patient relationship are reproduced in the nursing home-resident relationship. Both instances involve periods of vulnerability, as the conditions that trigger the need for nursing home care often leave residents vulnerable. Both instances also involve high levels of trust involving the other party's superior knowledge. Both instances involve sharing personal and sensitive information about yourself to another person. Both instances involve exchanges for large sum of money. As a society we expect nursing homes to take care of our loved ones: provide them with clean water and safe food, clean, maintain safe and sterile environment, supervise that they take their medication and even help them in using the bathroom.[111] We hope and believe the nursing home is our partner in this transition. Nursing homes provide more than just commercial services (like an ordinary contract); indeed, it is hard to imagine a greater relationship of trust. And, like in the physician context, the sum of money being exchanged is hardly nominal:

New York Region[112]	Nursing Home's Regional Daily Rate	Nursing Home's Annual Rate
Central	$288	$105,216
Long Island	$407	$148,680
New York City	$389	$142,116
Northeastern	$310	$112,968

Northern Metropolitan	$377	$137,460
Western – Buffalo	$310	$113,304
Western – Rochester	$350	$127,920

Consent for an arbitration clause should be invalidated due to "undue influence" as part of the residents' expectation of trust with their nursing home. There are numerous and readily apparent ways in which a mandatory arbitration clause benefits the nursing home, but not the nursing home resident. In particular, the confidentiality or lack of reporting on a decision of arbitration prevents state agencies from policing and remedying a nursing home's substandard quality of care.[113] Arbitration is being put forth for the nursing home's benefit and the nursing home resident's detriment. Therefore, the special relationship between the parties in the nursing home context should give rise to the judiciary taking a more critical review of the prospective resident's consent.

In conclusion, nursing homes and their residents share the similar qualities of trust and control where, as in malpractice waivers and prisons, society scrutinizes a person's consent. So the final question that remains is whether there is a reason for the judicial disconnect that treats arbitration and nursing homes so differently from waivers of medical malpractice? This author purposes several possible reasons: (1) the existence of the Federal Arbitration Act (FAA); (2) an acceptance of the process of arbitration; (3) as opposed to limiting malpractice liability, recognition that arbitration is beneficial in the nursing home context.

1. Judicial Disconnect and the Federal Arbitration Act

The Supreme Court has described the FAA as embodying a "liberal federal policy favoring arbitration agreements."[114] The FAA was originally enacted in 1925[115] to counter "widespread judicial hostility to arbitration agreements."[116] According to the U.S. Senate Judiciary Chairman in 1924, English courts saw arbitration clauses as attempts to remove judicial intervention. In a series of hearings, the Senate Judiciary Committee sought testimony on the arbitration process. Testimony presented arbitration's benefits as speedier, more convenient and less expensive than litigation.[117] The examples used to illustrate arbitration involved commercial entities, often of similar business sophistication,[118] unlike a prospective resident and nursing home. Arbitration was also presented as a "purely voluntary"[119] decision between the parties, a qualifier that the ABA has expressed to never actually apply in the context of nursing homes arrangements.[120] Arbitration was also presented as something *face-to-face* and would be less adversarial than litigation,[121] an unfitting statement when one recalls the wrongful death claim from New York discussed earlier.[122]

As a technical matter, the Act should not prevent judges from invoking duress, undue influence or unconscionability as justifications to void an arbitration clause. The Act provides a potential escape clause for judges: that "[a] written provision in...a contract...to settle by arbitration a controversy thereafter arising out of such contract... shall be valid, irrevocable, and enforceable."[123] The Act's "saving clause," however, states that arbitration agreements are enforceable "save upon such grounds as exist at law or in equity for the revocation of any contract."[124] Common legal doctrines invoked to revoke contractual consent include: lack of mutual consent, duress and undue influence. But as a pragmatic matter, judges are likely hesitant to invalidate arbitration clauses as a result of the FAA.

Despite the Act's "saving clause" the Supreme Court has repeatedly strengthened the FAA. The Supreme Court has decided that arbitrators must first hear challenge(s) to the legality of the contract,[125] that arbitration is valid in the areas of employment discrimination disputes[126] and in securities transactions[127] (despite both areas being routinely subjected to federal intervention) and may restrict class action remedies.[128] Recently, the Supreme Court has rejected unconscionability as a defense to invalidate arbitration clauses that foreclose class-wide remedies.[129] While there is some understandable hesitation as to why courts may be reluctant to invoke undue influence on arbitration clauses due to the FAA,[130] the "savings clause" gives judges enough flexibility in possibly voiding them that it cannot be the sole explanation.

2. Judicial Disconnect and Arbitration as a Different Construct Than Limitations on Liability

Indeed, this author feels the second reason is perhaps the strongest: an acceptance, or an apparent disconnect, on the nature of the arbitration process as compared to overt attempts to limit liability. The Model Rules of Professional Responsibility (for attorneys) prohibit a lawyer from making an agreement limiting the lawyer's liability to a client, such as a prospective waiver of legal malpractice, unless the client is independently represented by separate counsel when making the agreement.[131] However, the Model Rules find it to be perfectly acceptable to hold clients to a prospective arbitration agreement, as long as they are informed.[132, 133] Society simply does not view consenting to arbitration as carrying the same threat of imbalance bargaining power or undue influence as waivers of liability.

For practical purposes, arbitration is a waiver of liability. One of the most important differences between arbitration and bringing a claim in civil court is the contingent fee system that exists in personal injury claims. Under the contingent fee system in personal injury civil actions, the attorney representing the plaintiff is only paid

attorney fees if the claim is successful. A plaintiff, who has already been injured, does not have to take financial risks to pursue justice. However, under arbitration, a resident may have to have an attorney upfront to take the case. Additionally, most arbitration curtails discovery, leaving the resident with less and less evidence he or she can present to the arbitration panel. Here, the contingent fee is particularly important because a plaintiff's trial attorney is not only a litigator, but also an investigator—and this can make the critical difference for justice.

In a recent New York case,[134] the court took notice of a Consumer Financial Protection Bureau's (CFPB) report to Congress regarding the use of arbitration clauses in consumer transactions.[135] The court reproduced the Report's finding that "arbitration clauses used by companies to avoid lawsuits take away consumers' rights to sue in court and offer little, if any, benefit to consumers."[136] The study found, for example, that companies prevailed in 70% to 90% of cases resolved by arbitrators, depending on the type of arbitration.[137] Another study concluded that plaintiffs receive on average 35% less than if they went to trial.[138] Although perhaps plaintiffs receiving less compensation for the damages provides a net benefit for society, as the next section will examine.

3. Judicial Disconnect and Arbitration as a Benefit

"All residents in long-term care facilities are sick," declared defense attorney Joel Fishbein in his article defending the use of arbitration clauses in nursing home agreements.[139] Nursing homes are already expensive, Fishbein maintains, and there are ongoing concerns about their affordability. By lifting the protection of arbitration clauses, their costs will only go up. Arbitration lacks a jury and therefore minimizes the susceptibility of the verdict to emotional appeals. Many of the emotional arguments invoked in this article, such as the dread of putting a loved one in a nursing home, are the same arguments that defense attorneys fear will sway a jury to reward extraordinary damages. For example, Fishbein cites an Arkansas nursing home case where the jury awarded $15.4 million in compensatory damages, $25,000 for breach of contract and $63 million in punitive damages.[140] Nursing homes would shift the cost of litigation and jury verdicts on to the prospective residents, thus further raising the (already expensive) cost of nursing home care, if not bankrupting the nursing home. Therefore, Fishbein concludes that society benefits from buffering the costs of litigation and liability on nursing homes through the use of arbitration.

These arguments are nothing new; they have been repeatedly invoked in calls to reform the judiciary system for medical malpractice cases, such as placing a cap on punitive damages for medical malpractice rewards.[141] As discussed, there is inconclusive evidence to support that malpractice premiums are lower in states with malpractice caps.[142] Regardless, conventional wisdom says that companies will shift costs to the consumer. So maybe there is a reasonable middle ground? Originally, this article was to provide a middle-ground solution and how increasing transparency in this area may jolt market forces. However, as this article was being drafted the federal government intervened in this area and outright banned pre-dispute arbitration agreements in nursing home admissions.

4. Judicial Disconnect and Federal Government Intervention

Ultimately, in October of 2016 the federal government, the Center for Medicare and Medicaid Services (CMS), the office responsible for Medicare and Medicaid within Health and Human Services, sought to stop federal funds from going to nursing homes utilizing arbitration clauses. The move was very controversial; even CMS expressed hesitation when it first proposed the regulations and suggested it might not be a full prohibition. Less than a month after the regulation was finalized, the legality of the regulation has already been challenged.

Before discussing the history of the rules and the legal challenges that they may face, it is prudent to explain the authority of CMS. CMS does not have the authority on what creates a binding arbitration agreement; instead, it can impose "conditions of participation" to receive federal money from the Medicare and Medicaid program. Therefore, CMS' regulations impose requirements should the nursing home still wish to receive federal funding.

In 2015, CMS proposed regulations on how nursing homes may use arbitration agreements.[143] These proposed regulations discussed requirements, such as requiring the arbitration agreement to be in a separate document for signature.[144] As discussed above, some courts, when looking for unconscionability, do take into account whether the arbitration agreement was in a separate document. The American Health Care Association (AHCA) came out against the proposed regulations and stated that many of these practices have already been implemented into practice (although that begs the question as to why they are against they regulations if they were already moot).[145]

When the rules were proposed, at least 50 public interest organizations, 15 state attorneys general and 34 senators called to ban pre-dispute arbitration agreements entirely.[146] CMS considered banning arbitration clauses outright but said that "arbitration is favored by the courts and provides both parties, the resident and the nursing home, with advantages."[147] This statement suggests a tacit understanding that an outright ban on arbitration would clash with the Supreme Court's long jurisprudence on favoring the Federal Arbitration Act. Despite the above proposals, CMS sought comments on whether the regulations were not going far enough, especially in cases where "if the resident is hospitalized and needs to locate a facility quickly, they may feel more pressure to accept such an agreement."[148]

Recently, the proposed regulations were codified in a final rule.[149] In the final rule, CMS banned pre-dispute arbitration agreements, regardless of whether they were a requisite to admission. CMS explained that it had the authority to issue the final rule because it does not affect existing agreements and only regulates "the conditions of adoption of such agreements." CMS can state the conditions to participate in the Medicare and Medicaid programs. Thus, binding, pre-dispute arbitration agreements, even if they were mandatory for admission, cannot be used by nursing homes and assisted living facilities after Phase 1 of the rule was implemented on November 28, 2016.

The legality of the regulations were challenged in federal court. On October 17, the AHCA filed a federal lawsuit against HHS and CMS, challenging the legality of the rule prohibiting pre-dispute arbitration provisions. The AHCA is a not-for-profit federation of affiliated state organizations representing long-term care providers. Specifically, the AHCA, along with its Mississippi affiliate association and additional Mississippi and Texas providers, are the plaintiffs in the case. The plaintiffs requested an entry of a declaratory judgment that the Arbitration Rule is unlawful and entry of orders preliminarily and permanently enjoining CMS and HHS from enforcing the Arbitration Rule when it is scheduled to be effective on November 28. Their argument, much like how New York and West Virginia failed to broadly ban arbitration provisions, is that HHS and CMS is violating the Federal Arbitration Act (FAA) to enter into arbitration agreements. The plaintiffs further argued that even if such a prohibition were legally permissible, the Arbitration Rule is arbitrary and capricious, and thus unlawful.

A judge in the U.S. District Court for the Northern District of Mississippi in November granted a request by the AHCA and four other state and local health care groups for an injunction.[150] The ban was slated to go into effect sometime late November in 2016. Later that December, CMS sent a memo to states and Medicare contractors stating that the agency will not enforce the ban until the injunction is lifted.[151] The Trump Administration's stance for less federal government regulation seems to suggest that CMS' final rule does not have much of a bright future.

The uncertainty surrounding CMS' decision amplifies the nuanced legal, policy and ethical issues surrounding the future of long-term care in America. Making decisions on where to place a family member invokes a range of emotions and can involve immediacy, technical complexity, and competing priorities. The nature of the nursing home admissions process, the necessity to trust other individuals, combined with the important rights that prospective residents and their families may unwittingly waive, present many of the same concerns for why courts are skeptical of medical malpractice waivers. Judges should fight this disconnect and be more willing to intervene, and especially critical of the confidentiality or lack of transparency on the arbitration process. Absent judicial intervention, legislators and other political actors should consider modifying or regulating the arbitration process such as the prohibiting a confidentiality requirement or requiring arbitrators to publish their result to the public. Should a prospective nursing home resident be willing to give up his or her access to the civil justice system for admission, it should only be allowed in circumstances where there is absolutely no doubt, with no baseline assumptions that the clause was negotiable, to ensure the resident was presented with a meaningful choice.

Endnotes

1. From what this author understands, "nursing facilities" or "long term care facilities" are the now preferred business terms; however the author is using the term "nursing home" due to the term's familiarity.
2. The author also acknowledges that there is a wide range of what a layperson considers to be a nursing home, including independent living communities, nursing facilities and even hospice.
3. *Cost of Care Survey*, Genworth Fin. Inc. (2015), https://www.genworth.com/dam/Americas/US/PDFs/Consumer/corporate/130568_040115_gnw.pdf (last visited March 17, 2016).
4. *See generally* Official judge judy website, www.judgejudy.com.
5. *See generally* Michelle Andrews, *Signing a Mandatory Arbitration Agreement with a Nursing Home can be Troublesome*, Washington post (Sep. 17, 2012), https://www.washingtonpost.com/national/health-science/signing-a-mandatory-arbitration-agreement-with-a-nursing-home-can-be-troublesome/2012/09/16/ccf851ba-6a2c-11e1-acc6-32fefc7ccd67_story.html.
6. *ReliaStar Life Ins. Co. of N.Y. v. EMC Nat'l Life Co.*, 564 F.3d 81, 86 (2d Cir. 2009) (stating the rule that "As long as the arbitrator is even arguably construing or applying the contract and acting within the scope of his authority, a court's conviction that the arbitrator has committed serious error in resolving the disputed issue does not suffice to overturn his decision.") (citing U*nited Paperworkers Int'l Union AFL-CIO v. Misco, Inc.*, 484 U.S. 29, 38 (1987)).
7. Michael Corkery & Jessica Silver-Greenberg, *Pivotal Nursing Home Suit Raises a Simple Question: Who Signed the Contract?*, n.y. times (Feb. 21, 2016), http://www.nytimes.com/2016/02/22/business/dealbook/pivotal-nursing-home-suit-raises-a-simple-question-who-signed-the-contract.html (last visited March 23, 2016).
8. *Id.*
9. The results of arbitration are difficult to find as many are unpublicized and not made available to the public.
10. heritage ministries, *Comment Letter on Proposed Reform of Requirements for Long Term Care Facilities* (Oct. 9, 2015), https://www.regulations.gov/contentStreamer?documentId=CMS-2015-0083-9813&attachmentNumber=1&disposition=attachment&contentType=pdf (submitting to CMS that they "receive admissions too soon (as the hospital wishes to reduce their length of stay and thus their cost.)").
11. Linda S. Whitton, *Navigating the Hazards of the Eldercare Continuum*, 6 J. Mental health & aging 145, 148 (2000) (arguing that after federal changes in the 2000s that hospitals discharge planning occurs "earlier… quicker and sicker.").
12. Denese Ashbaugh Vlosky, et al., "*Say-so" as a Predictor of Nursing Home Readiness*, 93 J. of fam. & Consumer Scis. 59 (2001).
13. *See, e.g.*, Ann E. Krasuski, *Mandatory Arbitration Agreements Do Not Belong in Nursing Home Contracts with Residents*, 8 depaul J. Health Care L. 263, 280 (2004) ("[a]dmitting a loved one to a

nursing home is an overwhelming and stressful undertaking for families . . . . If families give any thought to the admissions agreement they are signing, they probably do not consider whether it contains a mandatory arbitration agreement").

14. And will be discussed in greater detail shortly later on.

15. ABA COMM'N ON LAW AND AGING, *Report, Recommendations and Exec. Summary* (Feb. 16, 2009), http://www.americanbar.org/content/dam/aba/directories/policy/2009_my_111b.authcheckdam.pdf.

16. Arbitration Fairness Act of 2015, H.R. 2087, 114th Cong. (2014), Arbitration Fairness Act of 2014, S.878 113th Cong. (2013), Fairness in Nursing Home Arbitration Act, S. 2838, 110th Cong. (2008).

17. Press Release, SENATOR AL FRANKEN, *Sen. Franken Leads Group of 34 Senators Calling on Medicare & Medicaid to Ban Long-Term Care Facilities from Using Unfair Arbitration Contracts* (Sept. 23, 2015), https://www.franken.senate.gov/?p=press_release&id=3247 (last visited Mar. 23, 2016).

18. I imagine some legal realists may disagree with me here.

19. *See, e.g.*, *Madden v. Kaiser Found. Hosp.*, 17 Cal.3d 699, 710 (Cal. 1976) (stating that it is well established, in the absence of fraud, overreaching or excusable neglect, that those who sign an instrument may not avoid the impact of its terms on the ground that they failed to read the instrument before signing it); *Tampa HCP, LLC v. Bachor*, 72 So .3d 323, 326 (Fla. Dist. Ct. App. 2011) (holding, in part, that to the extent the daughter of the nursing home resident failed to read the agreement, nothing the nursing home did or said caused her failure read it); *Reno v. SunTrust, Inc.*, No. E2006–01641–COA–R3CV, 2007 WL 907256, at *3 (Tenn. Ct. App. Mar. 26, 2007) (stating that the law imparts a duty on the contractual parties to learn the contents and stipulations of a contract before signing it; therefore, signing it without learning such information is at the party's own peril).

20. To be more exact, if a contract has a severance clause, which many of them of do, then the judge may decide to just sever the clauses or provisions that are unconscionable and leave an enforceable contract, albeit a bit gutted.

21. *See generally* Contracts of Adhesion, BLACK'S LAW DICTIONARY, 318-319 (7th ed. 1999).

22. *See, e.g., Graham v. Scissor-Tail Inc.*, 623 P.2d 165, 172–3 (Cal. 1981) (observing that an adhesion contract that does not fall within the reasonable expectations of the weaker party or that is unduly oppressive will not be enforced against the weaker party); *Zigrang v. U.S. Bancorp Piper Jaffray, Inc.*, 123 P.3d 237, 241 (Mont. 2005) (same); *Taylor v. Butler*, 142 S.W.3d 277, 286 (Tenn. 2004) (same).

23. *See, e.g.*, *Higgins v. Spencer,* 531 So. 2d 768 (1st Cir. 1988) (listing the exceptions for the presumption of capacity to contract), *First. Nat. Bank of Shreveport v. Williams,* 346 So. 2d 257 (3rd Cir. 1977) (discussing the presumption of capacity to contract and the possible exceptions); *Simmons First Nat'l Bank v. Luzader*, 438 S.W.2d 25, 27 (Ark. 1969) (holding "[t]here is a presumption of law that every man is sane, fully competent and capable of understanding the nature and effect of his contracts"), *Olsen v. Hawkins,* 90 Idaho 28, 29 (Idaho 1965) (same).

24. *See generally Shotts v. OP Winter Haven, Inc.*, 80 So. 3d 456, 467 (Fla. 2011) (stating that substantive unconscionability is moot if there is no procedural unconscionability), *Fortune v. Castle Nursing Homes, Inc.*, 164 Ohio App.3d 689, 696 (Ohio Ct. App. 2005) (overturning a trial court's finding of unconscionability because, while there was substantive unconscionability, there was no procedural unconscionability), *Armendariz v. Found. Health Psychcare Serv., Inc.*, 6 P.3d 669, 690 (Cal. 2000) (noting that while both substantive and procedural unconscionability needs to be shown, they do not need to be shown to the same degree of severity).

25. As contract law is mostly a doctrine left to individual states, there is no uniform doctrine that accounts for all the states. It is not uncommon for states to adopt the same standard using the same language or the same standard using different language. For example, some states explain the standard for substantive unconscionability as a term/provision that would be a "shock to a person of common sense." *Philpot v. Tenn. Health Mgmt., Inc.*, 279 S.W.3d 573, 579 (Tenn. Ct. App. 2007). Ultimately, substantive unconscionability grapples with the reasonableness of the terms of the contract.

26. *See, e.g., Briarcliff Nursing Home, Inc. v. Turcotte*, 894 So. 2d 661 (Ala. 2004) (enforcing "even if there are only two nursing homes in [that county], [plaintiffs] have not asserted that an elderly person... lacks meaningful choice," in part, because plaintiffs did not prove that they would not be able to live in another county.)

27. *Hayes v. Oakridge Home,* 908 N.E.2d 408, 413 (Ohio 2009).

28. *Golden Gate Nat'l Senior Care, LLC v. Beavans*, CV-15-17, 2015 WL 5000886, at *7 (E.D. Pa. Aug. 20, 2015).

29. *See e.g., Tampa, supra* note 20 at at 326.

30. No. E2003-00068-COA-R9-CV., 2003 WL 23094413, at 1, 4 (Tenn.Ct. App. Dec. 30, 2003).

31. *Id.* at *3 (noting that "Ms. Nelson testified that, when she commented that reading the admission agreement would take a long time, the admissions coordinator said, "That's quite all right. I will explain [the admission agreement] to you." Despite the admissions coordinator's assurances, Ms. Nelson claimed that the admissions coordinator never mentioned mediation or arbitration or pointed out to her that, by signing the document, she was waiving Mr. Cox's right to a jury trial.").

32. *Covenant Health Rehab of Picayune, L.P. v. Brown*, 949 So. 2d 732 (Miss. 2007) (overruled on other grounds by *Covenant Health & Rehabilitation of Picayune, LP v. Estate of Moulds ex rel. Braddock*, 14 So. 3d 695 (Miss. 2009)).

33. *Broughsville v. OHECC, LLC*, 2005-Ohio-6733, 2005 WL 3483777, at *5 (Ohio Ct. App. Dec. 21, 2005). Interestingly, the Court never states the page length of the complete contract agreement.

34. *Woebse v. Health Care & Ret. Corp. of Am.*, 977 So. 2d 630 (Fla. Dist. Ct. App. 2008).

35. *Mitchell v. Kindred Healthcare Operating, Inc.*, No, W2008-00378-COA-R3-CV, 2008 WL 4936505 (Tenn. Ct. App. May 26, 2008), appeal denied, (May 26, 2009); *see also Dueñas v. Life Care Centers of Am., Inc.*, 336 P.3d 763 (Ariz. Ct. App. Div. 1 2014) (holding the same, that explanation is not necessary when the term is displayed conspicuously).

36. *Tender Loving Care Mgmt., Inc. v. Sherls*, 14 N.E.3d 67 (Ind. Ct. App. 2014).

37. *Gainesville Health Care Center, Inc. v. Weston*, 857 So. 2d 278, 285-6 (Fla. Dist. Ct. App. 2003).

38. *Greenbrook NH, LLC v. Estate of Sayre,* 150 So. 3d 878, 882 (Fla. Dist. Ct. App. 2014).

39. *See Mitchell v. Kindred Healthcare Operating, Inc.,* 349 S.W.3d 492 (Tenn. Ct. App. 2008), *appeal denied*, (May 26, 2009), *Garcia v. HCR ManorCare LLC*, No. 1743 MDA 2014, 2016 WL 127514 (Pa. Super. Ct. Jan. 12, 2016), *Tampa*, *supra* note 19 at 326.

40. *Bland, ex rel. Coker v. Health Care and Retirement Corp. of America*, 927 So. 2d 252 (Fla. Dist. Ct. App. 2006).

41. *See also THI of N.M. v. Lovato*, 848 F.Supp.2d 1309, 1326 (D.N.M. 2012) ("The Arbitration Agreement afforded Ms. Atencio three days to revoke the agreement for any reason or no reason at all, thus relieving any pressure she may have felt by signing it during a stressful time or without the counsel of an attorney." (internal citation omitted).

42. *Philpot, supra* note 25 at 583 (citing *Buraczynski v. Eyring*, 919 S.W.2d 314 (Tenn. 1996)).

43. *See* U.C.C. § 2-302 cmt. 1 (stating "[t]he principle is one of the prevention of oppression and unfair surprise (case citation omitted) and not of disturbance of risks because of superior bargaining power").

44. Although appellant, the prospective resident, was not on equal footing with appellee in terms of bargaining power, "mere inequality of bargaining power is not a sufficient reason to hold an arbitration provision unenforceable." *Broughsville, supra* note 33, at *4 (citing *Neubrander v. Dean Witter Reynolds, Inc*., 610 N.E.2d 1089, 1091 (Ohio Ct. App. 1992)).

45. *Mitchell*, *supra* note 39.

46. *Hayes, supra* note 27 at 414.

47. *Rinderle v. Whispering Pines Health Care Ctr.*, 12th Dist. No. CA2007–12–041, 2008 WL 3823701 (Ohio Ct. App. Aug. 18, 2008).

48. *Golden Gate National Senior Care, LLC v. Beavens,* 123 F.Supp.3d 619 (E.D. Pa..2015).

49. *Romano ex rel. Romano v. Manor Care, Inc*., 861 So. 2d 59 (Fla. Dist. Ct. App. 4th Dist. 2003).

50. *See infra* note 115.

51. *Marmet Health Care Ctr., Inc. v. Brown*, 132 S. Ct. 1201 (2012) (per curiam).

52. *Brown v. Genesis Healthcare Corp.*, 229 W.Va. 382 (W. Va. 2012) (upholding in part and reversing in part after the Supreme Court's per curiam opinion). *See generally West Virginia Supreme Court Affirms That Unconscionability Doctrine Applies to Nursing Home Contracts With Arbitration Clauses*, Wolfe law firm (June 20, 2012), https://www.westvirginiainjurylawyerblog.com/2012/06/in-response-to-the-united.html.

53. *Berkson v. GOGO LLC*, 97 F.Supp.3d 359, 388 (E.D.N.Y. 2015).

54. *See generally* Collen McCullough, *Unconscionability as a Coherent Legal Concept*, 164 U. Pa. L. Rev. 779 (Feb. 2016). Although it should be worth noting that credit card agreements with consumers is an area where there is a federal oversight.

55. *See, e.g., Vicksburg Partners, L.P. v. Stephens,* 911 So. 2d 507, 516 (Miss. 2005) (discussing that while the presence of a contract of adhesion is important, it is not enough to solely substantiate a finding that the arbitration clause made the admissions agreement unconscionable) (overruled on other grounds by *Covenant Health & Rehabilitation of Picayune, LP v. Estate of Moulds ex rel. Braddock*, 14 So. 3d 695, 50 A.L.R.6th 621 (Miss. 2009)).

56. *See, e.g., Mitchell, supra* note 39.

57. *But see infra* note 66 (concluding that nursing homes do not treat them as voluntary despite labeling them as such).

58. *Bedford Health Properties, LLC v. Estate of Davis ex rel. Davis*, 50 So. 3d 362 (Miss. Ct. App. 2010).

59. *Vicksburg Partners*, *supra* note 55.

60. *Id.*

61. SA–PG Sun City Ctr., LLC v. Kennedy, 79 So. 3d 916, 919 (Fla. Dist. Ct. App. 2012).

62. *Weston*, *supra* note 37 at 284.

63. *Bachor, supra* note 19 at 326.

64. *Broughsville, supra* note 33 at *5.

65. *Wascovich v. Personacare of Ohio, Inc.*, 943 N.E.2d 1030, 1037 (Ohio Ct. App. 2010) (noting that "Appellant has also put forth evidence that the arbitration agreement is adhesive in nature…. that no resident has ever made changes to the agreement.").

66. Lisa Tripp, *Arbitration Agreements Used by Nursing Homes: An Empirical Study and Critique of AT&T Mobility v. Concepcion* (2011), *available at* http://ssrn.com/abstract=1884279.

67. *See, e.g., THI of Pa. at Mountainview, LLC. V. McLaughlin ex. rel McLauglin*, No. 14-CV-1616, 2015 WL 2106105, at *6 (W.D. Pa. May 6, 2015*), Broadnax v. Quince Nursing & Rehab. Ctr., LLC*, No. W200802130COAR3CV, 2009 WL 2425959, at *3 (Tenn. Ct. App. Aug. 10, 2009), *Figueroa v. THI of New Mexico at Casa Arena Blanca, LLC.*, 306 P.3d 480, 487-8 (N.M. Ct. App. 2012), *Oesterle v. Atria Mgm't Co., LLC*, No. 09–4010–JAR, 2009 WL 2043492 (D.Kan., Jul. 14, 2009).

68. restatement (Second) of Contracts § 177 (Am. Law. Inst. 1981).

69. *See generally* Christopher W. Kammer et al., *Understanding Fiduciary Duty*, 84 fla. b.j. 20 (Mar. 2010); *see also* DeMott, *Breach of Fiduciary Duty: On Justifiable Expectations of Loyalty and Their Consequences*, 48 ariz. l. rev. 925, 934–35 (2006).

70. *Id.*

71. *Compare Gordon v. Bialystoker Center and Bikur Cholim, Inc.*, 45 N.Y.2d 692 (N.Y. 1978); *Petre v. Living Centers-East, Inc*., 935 F. Supp. 808 (E.D.La. 1996) *with Zaborowski v. Hosp. Care Center of Hermitage Inc*., 60 Pa. D. & C.4th 474, 483-84 (Mercer Cty. 2002).

72. *Gordon,* 45 N.Y.2d at 698.

73. 763 S.E.2d 73 (W. Va. 2014).

74. *Id.* at 77.

75. *See generally* C.S. Patrinelis, Annotation, *Undue Influence in Nontestamentary Gift to Clergymen, Spiritual Adviser, or Church*, 14 A.L.R.2d 649, 657 (1950) (discussing different models of undue influence in gifts to religious advisers, noting that some cases did involve a fiduciary duty while others did not).

76. *See The Bible Speaks v. Dovydenas*, 81 B.R. 750, 760 (Bankr. D. Mass. 1988), *aff'd inpart, rev'd in part*, 69 F.2d 628 (Bankr. 1st Cir.), *cert denied*, 493 U.S. 816 (1989) (performing an undue influence analysis on pastor's effects on patron in the absence of a fiduciary duty); *Held v. Florida Conference Ass'n of Seventh Day Adventists*, 193 So. 828, 832-33 (Fla. 1940) (same; stating that undue influence is not strictly confined to fiduciary relationships).

77. *See, e.g., id.* (stating that undue influence is especially appropriate when there is a mental superiority, when one party is enfeebled in mind and body, or by disease or old age, the person obtaining such advantage will be required to show that the transaction was a fair one). *Dowie v. Driscoll*, 68 N.E. 56, 56 (Ill. 1903) (ordering an action to set aside transfer of property by 90-year-old widower); *Good v. Zook*, 88 N.W. 376, 378-79 (Iowa 1901) (ordering an action to set aside transfer of trust deed and promissory note by 87-year-old donor).

78. No. 5–12–0095, 2012 WL 7109677, at *1 (Ill. Ct. App. Nov. 2, 2012).

79. *Id.* at *4. (noting "it appears that neither the appellate courts nor the Illinois Supreme Court has ever cited to section 177 [undue influence] of the Restatement (Second) of Contracts in this regard."

80. *Id.* at *4-5.

81. *See, e.g., Thornton v. Allenbrooke Nursing & Rehab. Ctr., LLC*, No. W2007–00950–COA–R3–CV, 2008 WL 2687697, at *5 (Tenn. Ct. App. Jul. 3, 2008); *SSC Montgomery Cedar Crest Operating Co. v. Bolding*, 130 So. 3d 1194 (Ala. 2013).

82. Analyses on whether a family member has power of attorney are more complex than this article presents the issue and are outside the scope of this article. For example, Ohio provides power of attorney for "health care decisions" while it may include nursing home agreements; it may not include pre-injury arbitration agreements. *Compare* Ohio R.C. 1337.12(A)(1) *with Dickerson v. Longoria*, 414 Md. 419, 444-448, 995 A.2d 721 (Md. Ct. App. 2010) (holding that unless the arbitration is a condition of admission for the nursing home there was no power of attorney). *See also Primmer v. Healthcare Indus. Corp*., 43 NE.3d 788, 796 (Ohio Ct. App. 2014) (finding a daughter did not have apparent power of attorney simply because she signed the nursing home paperwork for admission); *Hendrix v. Life Care Ctr. of America, Inc.*, No. E2006-02288-COA-R3-CV, 2007 WL 4523876 (Tenn. Ct. App. Dec. 21, 2007) (affirming trial court's decision that daughter did not have power of attorney to bind mother to arbitration in nursing home contract).

83. 564 N.Y.S.2d 308, 310 (App. Div. 1990).

84. *Abramowitz v. N.Y. Univ. Dental Ctr., Coll. of Dentistry*, 494 N.Y.S.2d 721, 722, 724 (App. Div. 1985) (invalidating agreement because language was not specific).

85. Thomas A. Moore & Matthew Gaier, *Courts Disfavor Exculpatory Releases*, N.Y. L.J., 7 (Oct. 6, 1998) (describing history of the *Ash* case).

86. *Ash,* 564 N.Y.2d at 309 (citing *Morabito v. N.Y. Univ. Dental Ctr.*, 481 N.Y.S.2d 936 (App. Div. 1984) (unpublished table decision)).

87. *Id.* at 309-10.

88. *Id*. at 313 (stating the court was "in full agreement with the foregoing conclusions and analyses which are consistent with the majority view in this country that an exculpatory clause of the type here in issue must be held invalid as a matter of public policy") (citation omitted); *see also, e.g., Tunkl v. Regents of the Univ. of Cal.*, 383 P.2d 441, 441–42 (Cal. 1963) (finding exculpatory agreement invalid because it "affects the public interest"); *Clark v. Brooks*, 377 A.2d 365, 374 (Del. Super. Ct. 1977) (finding that language of release did not bar plaintiff's claim against defendant); *Olson v. Molzen*, 558 S.W.2d 429, 432 (Tenn. 1977) (holding that exculpatory contract between patient and doctor was void based on public policy grounds).

89. *Id.* at 310.

90. Harm is a requirement to stand before a judge/judicial authority; therefore, judges will only ever examine exculpatory clauses in cases where the plaintiff claims to have suffered an injury rather than in hypothetical injuries.

91. *See generally* Timothy Lytton and Tom Baker, *Allowing Patients to Waive the Right to Sue for Medical Malpractice: A Response to Thaler and Sunstein* (2010) 254 Faculty Scholarship Repository, 6, 8.

92. *See, e.g.,* Kathryn Zeiler, *Turning from Damage Caps to Information Disclosure: An Alternative to Tort Reform*, 5 Yale J. Health Pol'y L. & Ethics 385, 391-94 (2005) (noting that empirical studies linking damages caps and rates charged for medical malpractice insurance premiums are inconclusive); *see also Weiss Rating: Caps Fail to Contain Malpractice Cost Increases*, S. Fla. Bus. J. (June 2, 2003), http://www.bizjournals.com/southflorida/stories/2003/06/02/daily3.html?page=all.

93. Economic and Budget Issue Brief, *Limiting Tort Liability for Medical Malpractice,* Congressional Budget Office (Jan. 8, 2004), http://www.americanbar.org/content/dam/aba/migrated/2011_build/medical_liability/01-08-MedicalMalpractice.authcheckdam.pdf (discussing the economic efficiency and equity benefits of spreading the cost of malpractice amongst society through insurance).

94. *See, e.g., The Legal and Ethical Environment of Business,* Chp 4.3 (2012) published by Saylor Academy, https://saylordotorg.github.io/text_the-legal-and-ethical-environment-of-business/s07-03-arbitration.html (stating that almost all credit card companies contain an arbitration clause); Jessica Silver-Greenberg & Robert Gebeloff, *Arbitration Everywhere, Stacking the Deck of Justice,* N.Y. Times (Oct. 31, 2015), http://www.nytimes.com/2015/11/01/business/dealbook/arbitration-everywhere-stacking-the-deck-of-justice.html (examining the arbitration clauses that are used by Bank of America, Chase, Citigroup, Discover).

95. *Brown, supra* note 52.

96. *Marmet, supra* note 51.

97. As an indirect result, the Supreme Court for the first time established that arbitration can apply to pre-dispute agreements regarding medical claims.

98. Michael Petro, *Nursing home arbitration enforceable in NYS,* Buffalo L.J. Blog (Jul. 27, 2015), http://www.bizjournals.com/buffalo/blog/buffalo-law-journal/2015/07/nursing-home-arbitration-enforceable-in-nys.html?s=print. But at the time of writing, New York has not amended the law. *Infra* note 116.

99. *See e.g., A.Z. v. B.Z.*, 431 Mass. 150 (Mass. 2000) (refusing to enforce a several decade old contract involving preembryos because it would make an individual a "parent over his present objection").

100. *See* Omnibus Budget Reconciliation Act of 1993, Pub.L. No. 103–66, § 13562, 107 Stat. 312, 596–605 ("Stark II"), Omnibus Budget Reconciliation Act of 1989. Pub.L. No. 101–239, § 6204, 103 Stat. 2106, 2236–44 ("Stark I"); *see also* 42 U.S.C. § 1320a-7b (Section 1128B(b) of the Social Security Act) (commonly referred to as the "Anti-kickback Statute").

101. The regulations implementing the Stark law define a "financial relationship," which may include "a direct or indirect compensation arrangement...with an entity that furnishes [designated health services]." 42 C.F.R. § 411.354(a)(1)(ii). A "compensation arrangement," in turn, can be "any arrangement involving remuneration, direct or indirect, between a physician... and an entity." *Id*. at § 411.354(c).

102. *See e.f., U.S. ex. rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3rd Cir. 2009) (finding a contractual agreement between anesthesiologists and hospital constituted a financial relationship under Stark that did not meet any exception).

103. Raisa Deber et al., *Do People Want to Be Autonomous Patients? Preferred Roles in Treatment Decision-Making in Several Patient Populations*, 10(3) Health Expectations, 248-58 (Sep. 2007).

104. There is much scholarly debate on how the patient-physician relationship should be structured and whether informed consent, or the law in general, preserves/hinders the ideal relationship. Regardless of that debate, this author is relying on these studies to merely suggest that individuals do not want to be wholly autonomous; instead they look for partners when making medical decisions.

105. *See generally* AMA Code of Medical Ethics (last rev'd 2001). Some states have adopted the AMA Code as their own Code for Medical Ethics. *See Murfreesboro Medical Clinical, P.A. v. Udom,* 166 SW3d 674 (Tenn. 2005) (noting Tennessee Board of Medical Examiners adopted the AMA Code of Medical Ethics) (citing Tenn. Code Ann. § 63–6–101 (1997)). Other professions that have a fiduciary duty to client, such as lawyers, also have their own rules of professional conduct.

106. Even the regulations prohibiting physician referrals based on a contractual agreement involving a financial relationship provide certain exceptions. *See generally* 42 C.F.R. § 411.357.

107. Scotty Y. Kim et al., *Power and Control: Contracts and the Patient-Physician Relationship*, 65 Int. J. Clin. Pract. 1214 (2011), http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3227003/.

108. *See generally* Tamar Frankel, *Fiduciary Duties as Default Rules,* 74 Or. L. Rev. 1209 (1995) (listing the boundaries of fiduciary relationship to include duress, coercion, undue influence).

109. Some individuals argue that people cannot make a detrimental decision for themselves and therefore we should never substitute our judgment with their judgment. The existence and definition of an "irrational decisions" have plagued social sciences, especially in the realm of suicide. *See generally* Valerie F. Reyna & Frank Farley, *Risk and Rationality in Adolescent Decision Making,* 7(1) Psych. Sci. in the Public Interest, 1-44 (2006) (detailing the history of scholarly thought on whether suicide should be seen as irrational or impulsive, yet rational, risk-taking behavior).

110. As discussed in the Undue Influence section of this article.

111. *See generally* Eric Parker, *Seven Things to Expect from a Nursing Home,* Chicagobridge (Feb. 23, 2011), http://www.thechicagobridge.org/seven-things-to-expect-from-a-nursing-home/ (listing honesty, prompt disclosures and a federally required care plan).

112. N.Y. Dep't of Health, *Estimated Average New York State Nursing Home Rates* (2016), https://www.health.ny.gov/facilities/nursing/estimated_average_rates.htm.

113. For example, in the legislative history for New York State's former statute that prohibited mandatory arbitration clauses in nursing homes indicates that the Legislature adopted this law in part specifically because it recognized the importance of the investigative process of a civil action. *McKinney's Public Health Law* § 2801-d, *N.Y. Pub. Health* § 2801-d (enacted 2009).

114. *Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24 (1983).

115. Codified as amended at 9 U.S.C. §§ 1–16 (2000 & Supp. V 2005).

116. *AT&T Mobility LLC v. Concepcion,* 131 S. Ct. 1740, 1745 (2011).

117. For example, Charles Bernheimer, a prominent arbitration figure, spoke at the pre-enactment hearings. Mr. Bernheimer was the Chairman of the Arbitration Committee of the Chamber of Commerce of the State of New York. The State of New York was on the cutting edge of arbitration when in 1920 New York enacted a statute similar to the proposed FAA. Bernheimer explained that "commercial bodies of the country" were pressing for the legislation promoting arbitration because "inexpensive but dependable arbitration" was preferable to "costly, time-consuming and troublesome litigation." He added that "the merchant finds that arbitration is a very direct and expeditious method" because while "[o]ur courts are so clogged that it is sometimes years before they can reach a settlement...arbitration makes a prompt settlement." *Hearing on S. 4213 and S. 4214 Before the Subcomm. of the S. Comm. on the Judiciary*, 67th Cong. 15 (1923).

118. *See, e.g., Joint Hearings on S. 1005 and H.R. 646 Before the Subcomms. of the Comms. on the Judiciary*, 68th Cong. 29I (1924) (statement of Henry Eaton, American Fruit Growers, Inc.) (discussing arbitration in the use of a disagreement between two banks).

119. Alexander Rose (the Arbitration Society of America representative) said that "[a]rbitration...does not by any means seek to supplant the courts...because after all it is a purely voluntary thing." *Id.* at 26 (Statement of Alexander Rose).

120. *ABA Report, supra* note 15.

121. "When the two parties to a dispute...are face to face they see, in the presence of a third man, their respective viewpoints better than they did before. . . . They are on speaking terms again and on terms of willingness to listen to reason, which they were not before, when they were separated and did not see each other face to face. It is a state of mind that is developed by this." *1924 Joint Hearing* at 5 (Statement of Charles Bernheimer).

122. The Supreme Court has affirmed that arbitration may encompass wrongful death claims. *Marmet, supra* note 51.

123. 9 U.S.C § 2 (2012).

124. *Id.*

125. *Buckeye Check Cashing Inc. v. Cardegna*, 546 U.S. 440 (2006).

126. *Gilmer v. Interstate/Johnson Lane Corp.*, 500 U.S. 20, 24 (1991).

127. *Shearson/American Express Inc. v. McMahon*, 482 U.S. 220 (1987).

128. *AT&T Mobility LLC v. Concepcion*, 131 S. Ct. 1740 (2011).

129. *Marmet, supra* note 51.

130. *Id.* at 1748.

131. Model Rules of Prof'l Conduct R. 1.8(h)(1) (2009) (requiring counsel present for binding a prospective client to a malpractice waiver).

132. Model Rules of Prof'l Conduct R. 1.8 cmt 14 (2009) (stating the rule against malpractice waivers does not prohibit arbitration of malpractice claims, provided such agreements are normally enforceable and the client is fully informed of the scope and effect of the agreement).

133. The ABA passed a resolution against the use of arbitration clauses in nursing home contracts.

134. *Berkson, supra* note 53 at 392-3.

135. *See* Consumer Financial Protection Bureau, *Arbitration Study, Report to Congress* (2015) § 1: Introduction and Executive Summary *available at* files.consumerfinance.gov/f/201503_cfpb_arbitration-study-report-to-congress-2015.pdf.

136. *Id.* at 5-6. The report looked at a wide range of arbitration in various consumer contexts, including credit cards, student loans and mobile wireless contracts.

137. *Id.* at 9, 14, 21.

138. Porter Organization, *Arbitration Study,* (2009) 6, *available at* www.ahcancal.org/research_data/liability/Documents/2009ArbitrationStudy.pdf.

139. Joel I. Fishbein, *Not Inherently Unfair: Arbitration in the Long-Term Care Setting,* 54 Dri For Def. 8 (August, 2012), http://www.mccumberdaniels.com/userfiles/files/Attorney%20Articles/Arbitration%20in%20the%20Long%20Term%20Care%20Setting%20DRI%200812%20JIF.pdf.

140. *Sauer v. Advocat Inc. et al.*, No. CIV 2000-5 (Ark. Cir. Ct., Polk County, June 29, 2001). Although Fishbein fails to mention that on appeal the Supreme Court of Arkansas reduced the compensatory damages from $15 million to $5 million and the punitive damages from $63 million to $21 million. *Advocat, Inc. v. Sauer*, 353 Ark. 29, 65, 111 S.W.3d 346, 367 (2003), *cert denied*, 540 U.S. 1004 (2003).

141. CBO Brief, *supra* note 93.

142. Zeiler, *supra* note 92. *But see* Office of Tech. Assessment OTA–BP–H–1 19, *Impact of Legal Reforms on Medical Malpractice Costs* 64 (1993) (finding caps did lead to a lowering of premiums).

143. *Reform of Requirements for Long-Term Care Facilities*, 80 Fed. Reg. 42167 (Jul. 16, 2015) (to be codified at 42 C.F.R. p.t. 405, 431, 477).

144. 80 F.R. at 42211. (proposing that "any agreement for binding arbitration should not be contained within any other agreement or paperwork addressing any other issues. It should be a separate agreement in which the resident must make an affirmative choice to either accept or reject binding arbitration for disputes between the resident and the facility." *But see* Medicare advocacy, *Comment Letter on Proposed Reform of Requirements for Long Term Care Facilities* (Oct. 14, 2015), http://www.medicareadvocacy.org/comments-medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities/ (noting that these proposals, such as providing the arbitration clause in a separate document, do not appear in the text of the proposed regulations).

145. Ina Jaffe, *Suing a Nursing Home Could Get Easier Under Proposed Federal Rules* (Oct. 19, 2015), National Public Radio, available at http://www.npr.org/sections/health-shots/2015/10/19/449957318/suing-a-nursing-home-could-get-easier-under-proposed-federal-rules.

146. *Id.*

147. 80 F.R. at 42211.

148. *Id.*

149. CMS Reform of Requirements for Long-Term Care Facilities, 81 Fed. Reg. 68688 (Oct. 4, 2016) (to be codified at 42 C.F.R. pt. 483).

150. *Am. Health Care Ass'n v. Burwell*, No. 3:16-CV-00233, 2016 U.S. Dist. LEXIS 154110 (D. Miss. Nov. 7, 2016).

151. Memo, Health & Human Services, *Long-Term Care (LTC) Regulation: Enforcement of Rule Prohibiting Use of Pre-Dispute Binding Arbitration Agreements is Suspended so Long as Court Ordered Injunction Remains in Effect* (Dec. 9, 2016), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-17-12.pdf (last visited Mar. 23, 2017).

NEWS flash

What's Happening in the Section

New Officers

At the Health Law Section's Annual Meeting in January, the members elected the following officers, for terms beginning June 1, 2017.

Chair-Elect:	Robert Hussar
Vice-Chair:	Julia Goings-Perrot
Secretary:	Hermes Fernandez
Treasurer:	Karen Gallinari

The current Chair-Elect, Laurence Faulkner, will begin his term as Chair in June 2017. Laurence is Director of Corporate Compliance and General Counsel of ARC of Westchester County.

Upcoming Events

More information about these programs is available on the NYSBA.org website, under the Health Law Section tab.

Current Legal Issues Surrounding Eye, Tissue and Organ Donation in New York State

Friday, April 28, 2017
9:00 a.m. - 1:00 p.m.
Mount Sinai Hospital, Goldblum Auditorium
East 101st St.
New York, NY 10029

Presented by the New York State Bar Association (NYSBA) Health Law Section in partnership with the New York Alliance for Donation (NYAD). This program will address:

- the organ shortage, discussion of organ, eye and tissue allocation, statistics and importance of the subject.
- laws surrounding organ, eye and tissue donation: consents, refusals, family involvement, disputes.
- hospital policies and procedures and involvement of hospital counsel
- brain death and brain death guidelines, involvement with organ, eye and tissue donation

Rochester - Health Law Section 20th Anniversary Networking Reception and CLE

Thursday, May 4, 2017
3:30 p.m. - 5:30 p.m.
Harris Beach
99 Garnsey Rd.
Pittsford, NY 14534

One-hour CLE to be followed by a reception. Topic TBA.

NYC—Health Law Section 20th Anniversary Networking Reception and CLE

Thursday, May 4, 2017
Fox Rothschild
100 Park Avenue #1500
New York City
6 p.m. - 8 p.m.

One-hour CLE to be followed by a networking reception: Recent Regulatory Changes Affecting Healthcare Providers.

Buffalo—Health Law Section 20th Anniversary Networking Reception and CLE

Thursday, June 1, 2017
6 p.m. – 8 p.m.
Hodgson Russ LLP
The Guaranty Building
140 Pearl Street, Suite 140
Buffalo, NY 14202

Reception followed by one hour CLE on "AKS Safe Harbor Revisions: What Is the Impact in New York State?"

Representing Licensed Health Care Professionals in the Disciplinary Process

Thursday, June 1, 2017
9:00 a.m. – 12:45 p.m. | OEP74
New York Society of Security Analysts (NYSSA)
1540 Broadway, Suite 1010
New York, NY 10036

Live and Webcast.

Overall Planning Chairs: Joseph DeMarzo and Carolyn Shearer. Sponsored by the Committee on Continuing Legal Education and the Health Law Section of the New York State Bar Association.

Recent Events

- **Annual Meeting.** The Section's Annual Meeting was held at the New York Hilton Midtown, NYC on Wednesday January 25, 2017. Once again, the program was Hot Topics in Health Law.
(See photos on pages 34-35)

- **Albany—Health Law Section 20th Anniversary Member Reception and CLE Albany,** Thursday, April 06, 2017, Albany Law School. Speakers included Harold N. Iselin, Esq., Greenberg Traurig, LLP; Mark R. Ustin, Esq., Partner, Manatt Health; Richard J. Zahnleuter, Esq., NYS Health Department; Axel Alexandre Bernabe, Esq., Assistant Counsel to Governor Andrew M. Cuomo on Health.
- **Program Integrity and Enforcement: The Government Perspective,** Friday, March 24, 2017, The Yale Club of New York City, 50 Vanderbilt Avenue, New York, NY. Co-Sponsored by the New York City Bar Association Health Law Committee. Speakers included:
  - Kenneth M. Abell, Esq., Assistant U.S. Attorney, Chief, Healthcare Fraud, Civil Division, U.S. Attorney's Office for the Eastern District of New York.
  - Daniel Tehrani, Esq, Assistant U.S. Attorney, Securities and Commodities Fraud Task Force.
  - Christopher B. Harwood, Esq., Assistant U.S. Attorney, Co-Chief, Civil Frauds Unit, U.S. Attorney's Office for the Southern District of New York.
  - Shannon Jones, Esq., Assistant U.S. Attorney, Deputy Chief, Healthcare Fraud, Criminal Division, U.S. Attorney's Office for the Eastern District of New York.
  - Vicki L. Robinson, Esq., Senior Counselor for Policy, Office of Inspector General, U.S. Department of Health and Human Services.
  - Jay Speers, Esq., General Counsel, Medicaid Fraud Control Unit, Office of the New York State Attorney General.
  - Saratu Ghartey, Esq., Chief Program Accountability Officer, New York City Department of Social Services.
  - Lisa Landau, Esq., Bureau Chief, Health Care Bureau, Office of the New York State Attorney General.
  - Erin Ives, Acting First Deputy Medicaid Inspector General, New York State Office of the Medicaid Inspector General.

Welcome New Members

The following members joined the Health Law Section since publication of the last issue of the *Health Law Journal*.

First District
Laleh L. Alemzadeh
Sherrie Brown
Dolly Daniela Cardenas
Anta Cisse-Green
Manuel P English
Philip Z. Glorieux
Lee J. Hirsch
Veronica Mary Jackson
Puja Khare
Leo C. Kreizman
Diana Martinez
Monica Risi Merrill
Bindu R. Nair
Christine Marie Pallares
Lauren Grace Perry
Beth E. Roxland
Laura J. Siegel Puhala
Preethi Swamy
Mara Anne Wilber
Ioanna O. Zevgaras
Amanda Zink

Second District
Diana Acosta
Anca C. Adams
Karen Eng
Ryan H. Scott
Hon. Debra Silber

Third District
Glinnesa D. Gailliard
Henry M. Greenberg
Michel Kim
David E. Restrepo

Fourth District
Melissa Kay Dobson
Vicki J. Prager

Fifth District
Anastasia Marie Semel
Shelly Pei-lun Tsai
Stewart L. Weisman

Sixth District
Kathryn Connerton
Alice D. Decker
Philip Grommet

Eighth District
Danielle Becker
Mary Beimler
Jason T. Daniels
Lorraine Marie Duthe
Colleen E. Gough
Lindsay V. Heckler
Jesslyn Holbrook
Gerald J. Whalen, II

Ninth District
John J. Barbera
Maureen J. Cunningham
Beth M. Davis
Alexander Fear
Shari S.L. Hubner
Linda L. Kaumeyer
Robert B. Larson
Michele Elaine Lucas
Anu Paulose
Timothy E. Pavelka

Tenth District
Kathryn Nicole Andreolli
Leslie Berkoff
Ginamarie Depaula
Stacey L. Goldston
Michael L. Gurman
Geoffrey Kaiser
James J. Lillie
Wendy G. Marcari
Gregory Richard Mitchell
Seth Adam Nadel
Kathleen B. O'Donnell
David E. Richman
Pamela A. Smith
Alana Maureen Sullivan
Erica Sari Youngerman

Eleventh District
Kerri Elizabeth Cutry
Sade Forte
Christos Chris Philippos Moutousis

Twelfth District
Leah Roffman Goldband

Thirteenth District
Sofia Roohi Khalid
Victoria Smolyar
Katheleen Anne Sullivan

Out of State
David Bailen
Lauren Courtney Baillie
Allen Deepak Bass
Lindsay Borgeson
Brandon H. Carr-Montano
Dr. Susan O. Cassidy
Joseph Elmo Cauda
Carol S. Doty
Jennifer Marie Harkin
Joy Denise Hays
Erin M. Healy
Kevin M. Lastorino
Mary Medina
Michael S. Pixley
Natassia Megan Rozario
Jesse S. Taft
Elizabeth N. Tatung
James Andrew Wilkinson
Jonathan Seth Zelig

Section Committees and Chairs*

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

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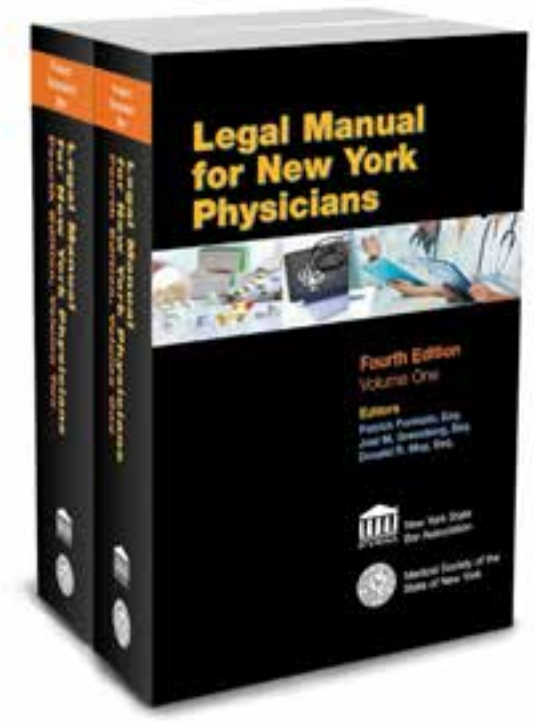

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