Health Law Journal

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Inside

A Message from the Section Chair 5 Lynn Stansel

Regular Features

In the New York State Courts 6
In the New York State Legislature 13
In the New York State Agencies 15
In the Journals 17
For Your Information 19

Feature Articles

Public Health Law § 2801-d and the Nursing Home Crisis: The Propriety of Invoking the Statute in Routine Negligence Cases 20 Andrew L. Zwerling

The Use of Pre-Dispute Arbitration Clauses in New York Nursing Home Agreements **26** *[ane Bello Burke]*

The Assisted Living Reform Act of 2004: New Models of Care, New Choices for Consumers 31 Alan J. Lawitz

Certificate of Need and Long-Term Care—Changes are Coming 41 *Jerome Levy*

The *Olmstead* Imperative: Judicial Interpretation of ADA and Federal-State Response 46 *Raul A. Tabora, Jr.*

A Social Ecology of Health Model in End-of-Life Decision-Making: Is the Law Therapeutic? ${\bf 51}$

Mary Beth Morrissey, JD, MPH and Bruce Jennings, MA

Article 81 Guardianship Obstacles for Petitioning Providers: Who Should Be Proposed As Guardian? Who Should Testify? **61** Alyssa M. Barreiro

Appellate Division Solidifies Legal Protection for Receivers—Recent Decision: Niagara Mohawk Power Corporation v. Anthony Salerno **65** *Jerauld E. Brydges and John M. Jennings*

Editor's Selected Court Decision

Blossom View Home v. Novello 68

State Government Reports

Dietary Supplements: Balancing Consumer Choice and Safety (Executive Summary) 74 The New York State Task Force on Life and the Law

Section Matters

Newsflash: What's Happening in the Section 78



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A Message from the Section Chair

The Fall meeting of the Health Law Section proved to be an even bigger success than we had anticipated. The feedback from the event, held at The Sagamore and attended by 100 lawyers, was almost universally positive, both from a social and programmatic perspective. Upon arriving home after the meeting, I allowed myself a few minutes to bask



in the glow of completion, and then turned to my next major project: fulfilling my duties as the "nut and candy" mother for my daughter's Brownie troop. My role as sales supervisor was not entirely voluntary—my daughter had been waitlisted for the troop (working mom missed an organizational meeting), and the offer to move her to the active roster appeared contingent upon my assuming what apparently was the least popular parental job. I soon learned why, as I spent Sunday and Monday (Halloween) evenings correcting addition errors of 8-year-olds and counting and re-counting the \$2,200 earned by the troop (much of it crumpled singles). Where are those MFCU auditors when you need them?

But then I am used to multitasking as I shift from one life sphere to another during each day, aided by cell phones, remote access and an excellent team. Somehow things usually hang together, as long as I keep any tendency towards perfectionism under wraps. Over the years, I've learned to ignore the messy closets and smile through a third consecutive night of macaroni and cheese, but most importantly I've learned to stand firm on my commitment to keep my child a top priority. That doesn't mean I don't put in the extra effort at work or the Section when required; it's really more a question of maintaining perspective and ruthlessly prioritizing.

I can draw on personal experience in setting that perspective, as I am descended from a long line of working mothers. All worked because they "had to," but were passionate about their careers. My paternal grandmother was a legal secretary who typed me letters on her Smith Corona at 60 words per minute. My maternal grandmother was a payroll clerk at a retail warehouse, although I spent the better part of my childhood believing that she ran the place, and until her retirement at 80 I expect she held the same belief. My

mother (now retired) was an elementary schoolteacher and a wonderful role model who blended work and home life seamlessly and who highlighted for me the personal satisfaction of working for the common good. I do not know to what extent my relatives experienced angst about balancing work and family life. I do know that I grew up believing that my career should be both fun and fulfilling, and that expectation ultimately brought me to health law.

Many women lawyers must feel the same way about health law, judging by the numbers of women participating in Section conferences and committees. Some juggle work and family as I do; others have different life experiences. What strikes me as most significant is the fact that these women actively participate in meetings and in committees and frequently step into leadership roles. They bring their own perspectives and life experiences to bear in helping to shape the law in this critically important area.

Despite my recent "nut and candy" misadventure, I am generally very selective about what extra responsibilities I assume apart from work and parenting. Nevertheless, I have never regretted my decision five years ago to become active in the Health Law Section. The Section meets my career needs for both fun and fulfillment, and provides me with an opportunity for professional growth. The time commitment has varied depending on my role and particular projects, but has been manageable with other responsibilities, particularly given the able support of the Bar Association administrative staff.

While I continue to fantasize about that elusive month-long vacation, I am energized by the packed agenda of the Section and ideas I still need to pursue during my term as Chair. Like my relatives, I am passionate about what I do, and my goal is to pass along that gift to my daughter. But for now, it's a bedtime reading of *Anne of Green Gables* that needs my attention. I look forward to seeing all of you at the Annual Meeting on January 25th in New York City.

But before leaving, I want to thank the authors of the excellent articles in this Special Edition on Long-Term Care Law, and congratulate the Special Edition Editor, Cornelius Murray of O'Connell & Aronowitz. Great job, Neil.

Lynn Stansel

In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Rejects Challenge to For-Profit Conversion of Empire Blue Cross and Blue Shield

Consumers Union of U.S., Inc. v. *The State of New York.* The New York Court of Appeals has rejected a challenge to legislation that allowed the conversion of Empire HealthChoice, Inc., d/b/a Empire Blue Cross and Blue Shield ("Empire"), from a nonprofit to a for-profit corporation. The decision represents the final chapter in a six-year restructuring effort by Empire and upholds Chapter 1 of the Laws of 2002, the Health Care Workforce Recruitment and Retention Act ("Chapter 1"), which was written specifically to allow Empire's conversion.

As a for-profit corporation, the once financially beleaguered health care provider was able to stave off bankruptcy by raising capital in an initial public offering of its stock in November 2002. Under the restructuring plan, Empire transferred its assets to a series of newly formed for-profit subsidiary corporations in exchange for 100 percent of the subsidiaries' newly issued common stock. The transfer was followed by the initial public offering of shares in the new subsidiaries.

At issue was the disposition of Empire's assets upon conversion. Under New York's Not-For-Profit Corporation Law, a not-for-profit corporation may dissolve and then sell its assets with approval from the state Supreme Court, on notice to the Attorney General. The assets must be distributed to other "corporations or organizations engaged in activities substantially similar to those of the dissolved corporation."

Plaintiffs in this case included Empire subscribers whose premiums and benefits were allegedly affected negatively by the conversion, as well as several organizations that worked



with chronically ill patients; the organizations argued that their work would be made difficult if Empire's assets were no longer

dedicated to not-for-profit purposes.

The complaint alleged that Chapter 1 violated the United States Constitution because it deprived plaintiffs and Empire of property rights without due process of law; that it violated the New York State Constitution by effecting an unauthorized taking of Empire's and plaintiffs' private property interests; and that Empire's Board of Directors breached their fiduciary duties by agreeing to the conversion. Plaintiffs also argued that the conversion violated Article III. Section 17 of the New York State Constitution, the Exclusive Privileges Clause ("Article III") because the right to convert from a not-for-profit to a for-profit corporation was granted solely to Empire.

Plaintiffs also claimed that Chapter 1 violated Article I, Section 10 of the U.S. Constitution, which provides that no state shall pass a law "impairing the obligation of contracts." Plaintiffs argued that Empire's Certificate of Incorporation created a contract between Empire and the public, which was impaired by the enactment of Chapter 1 and the resulting conversion.

The common thread in each cause of action was the assertion that the not-for-profit assets remaining after the restructuring were not going to be used to further Empire's historic charitable purpose.

In a lengthy decision, the Appellate Court held that Chapter 1 does

not unduly interfere with Empire's property interests, and that there is a direct correlation between the state's interest in enacting Chapter 1, which is to ensure Empire's continued existence, and requiring that Empire's not-for-profit assets be used for public health purposes.

"Empire has traditionally functioned as both a financing device for hospitals and a means to make economical health care available to as many New Yorkers as possible," the Court stated. "The dedication of conversion assets to support public health programs and recruit and retain health care is wholly consistent with these activities."

Plaintiffs' due process claims under State and Federal law are based on the argument that Chapter 1 did not allow for any input from the public. The Court, however, noted that Empire itself chose to proceed with the conversion, that public hearings were held, and that the conversion was approved by the state's Superintendent of Insurance.

In response to plaintiffs' claim that Empire's board breached its fiduciary duty by converting to a for-profit corporation, the Court noted that Chapter 1 "supercedes all inconsistent common law and statutory duties." The Court also stated that if the board decided that conversion was necessary for Empire to remain viable then the business judgment rule, which bars judicial inquiry into actions taken by corporate directors in furtherance of corporate purposes, would bar plaintiffs' claims regardless of the existence of Chapter 1.

The Court also held that the Exclusive Privileges Clause did not apply to Chapter 1 because while the law did allow Empire to convert, it did not confer an exclusive privilege

since it did not authorize Empire to prevent others from seeking to convert under similar conditions, or promise Empire that other not-forprofits will not be granted similar rights.

Second Circuit Dismisses Antitrust Suit by Emergency Medicine Physicians Seeking to Change Board Certification Eligibility Criteria

Daniel v. American Bd. of Emergency Medicine, 2005 WL 2470530 (2d Cir. 2005). In this action, plaintiffs sought redress for being ineligible to take a certification exam to become board certified in emergency medicine. Plaintiffs appealed a judgment of the United States District Court for the Western District of New York that dismissed their suit for lack of antitrust standing. Defendant American Board of Emergency Medicine (ABEM) is a Michigan not-for-profit corporation that certifies physicians in emergency medicine. ABEM is a member of the American Board of Medical Specialties, an umbrella organization formed to assist the member specialty boards in fulfilling their missions.

Plaintiffs sued ABEM, 28 hospitals, and an additional not-for-profit association alleging that defendants colluded to restrain trade in connection with the practice of emergency medicine in violation of Section 1 of the Sherman Act, and to monopolize or attempt to monopolize the market for ABEM-certified and eligible doctors in violation of Section 2 of the Sherman Act. Plaintiffs specifically complained that the defendants manipulated the residency training requirement for ABEM certification for the purpose of limiting the number of doctors certified in emergency medicine. Such limitation, the suit alleged, guaranteed super-competitive compensation for ABEM-certified doctors, and denied such compensation to members of the plaintiff class.

Plaintiffs also claimed that some hospitals restrict their hiring to ABEM-certified physicians, while others base compensation and promotion decisions on ABEM certification. Presently, only physicians who have completed a residency program in emergency medicine are eligible to take the ABEM certification exam. Prior to 1988, physicians could also become eligible to take the certification exam by completing 7,000 hours and 60 months of practicing or teaching emergency medicine (the "practice track").

Defendants argued that the case was correctly dismissed not only for lack of antitrust standing but also for lack of personal jurisdiction and venue. The Court concluded as a matter of law, that plaintiffs failed to demonstrate that ABEM "transacts business" in the Western District of New York. The Court held that rather than transfer the case to a district where venue is proper, the Court would exercise its discretion to dismiss what it viewed as a meritless suit.

The Court identified four factors relevant to antitrust standing: an injury in fact (1) to plaintiffs' business or property; (2) that is not remote from or duplicative of that sustained by a more directly injured party; (3) that qualifies as an "antitrust injury;" and (4) that translates into reasonably quantifiable damages. The Court focused on the second and third factors, asking (i) whether the plaintiffs had adequately demonstrated that the alleged injury to their business or property is one that the antitrust laws were intended to prevent, and (ii) whether they qualified as efficient enforcers of the antitrust claims at issue. The Court emphasized that it has long and frequently been observed that the antitrust laws were enacted for the protection of competition, not competitors.

In addressing the first question, the Court followed the Seventh Circuit's analyses in *Sanjuan v. American* Board of Psychiatry and Neurology, Inc., 40 F.3d 247, 251-52 (7th Cir. 1995), which held that doctors suing under a similar theory did not state "an antitrust injury." In Sanjuan, plaintiffs were also doctors denied board certification in their field of medical specialty because they failed to pass the defendant's certification examination and wanted to change the oral part of the examination to a language other than English. The doctors claimed that as a result, they earned less than board-certified doctors. The Court held that plaintiffs who want to obtain a credential that will help them charge higher prices, have pled themselves out of Court on the antitrust claim, especially when the antitrust laws are designed to drive producer's prices down rather than up.

The Court used the same analysis in this case. Here, the doctors only sought to restore—temporarily—the practice track as an alternative to residency training, so that they can qualify for the ABEM exam, after which they are satisfied to have the certification door shut on any other test applicants. In sum, the Court held that by seeking relief that would permit them to join but not end the alleged exclusive arrangement, plaintiffs make plain that they are not complaining of an antitrust injury. In the Court's view, plaintiffs incorrectly used the antitrust laws to try to protect themselves against competitors, not against competition.

The Court also held that the plaintiffs were not efficient antitrust enforcers. The Court held that in this case, where plaintiffs sue for both money damages and injunctive relief, one factor raises particular standing concerns: the presence of other efficient antitrust enforcers whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement. Here the Court held that plaintiffs have no natural economic self-interest in reducing the cost of emergency medical care to consumers. The

Court noted that private and government health care insurers, which reimburse hospitals for millions of dollars in emergency care provided to thousands of covered patients, have a direct and undivided economic interest in obtaining lower costs, and thus would be more appropriate parties to bring such claims.

State Commission on Quality Care for the Mentally Disabled Does Not Have Authority to Subpoena Documents Held by Owners and Operators of Realty Holding Companies

Reckess v. New York State Commission on Quality Care for Mentally Disabled, 794 N.Y.S.2d 464 (3d Dep't, 2005). The Appellate Division, Third Department, recently held that the New York State Commission on Quality Care for the Mentally Disabled (CQC) does not have the authority to compel production of documents held by owners and operators of five adult homes in their capacity as officers of realty holding companies. The owners and operators, through a series of transactions, transferred ownership of the homes to five separately incorporated holding companies, which were also owned by the owners and operators of the adult homes. The properties were then leased back to the adult homes and refinanced through the holding companies. As a result of the refinancing, the rent charged to each of the adult homes increased exponentially.

The CQC discovered the rent increases, and requested access to each facility's mortgage and closing documents. The Court ruled that the subpoenas reached "beyond the scope of [the CQC's] authority; the subpoenaed documents were executed by [the owners and operators] in their capacity as officers of the realty holding companies and the information sought related to their private finances." The Court chose not to expand the CQC's power beyond the

specific statutory grant of authority found in Mental Hygiene Law §§ 45.09 and 45.10, which authorizes the CQC, in part, to issue and enforce subpoenas in the examination of the "programmatic and financial operations" of the adult homes (§ 45.10[a][2]). The Court held that, "[t]here is no authority permitting [the CQC] to subpoena the financial records of third parties who lease the land and buildings to the adult homes."

Noncompliance with Public Health Law Will Not Void Agreement Transferring Ownership in Ambulatory Surgery Center

Simaee v. Levi, 2005 WL 2521148 (2d Dep't, October 11, 2005). The Appellate Division, Second Department, recently held that noncompliance with the provisions of Public Health Law § 2801-a(4)(b)(I) will not void an agreement to transfer ownership in an ambulatory surgical center (ASC). Plaintiff entered into an agreement with defendants whereby he obtained the option to purchase a one-third interest in an ASC. The option agreement provided that approval from the Public Health Council must be obtained before the sale of any interest in the ASC. Public Health Law § 2801-a(4)(b)(i) provides that "[a]ny transfer, assignment or other disposition of ten percent or more of an interest or voting rights in a partnership or limited liability company, which is the operator of a hospital to a new partner or member, shall be approved by the public health council." The failure to comply with Article 28 of the Public Health Law subjects the operator of a facility within its purview to the possible revocation or suspension of its operating certificate (Public Health Law § 2806(1)).

The Court found, however, that Public Health Law § 2801-a(4)(b)(i) "does not provide that the failure to obtain the prior approval of the Public Health Council will render a transfer made without such approval

ineffective. . . ." The Court therefore held that plaintiff could sue on the option agreement, because "violation of a statute that is merely malum prohibitum will not necessarily render a contact illegal and unenforceable," and "forfeitures by operation of law are disfavored, particularly where a defaulting party seeks to raise illegality as a sword for personal gain rather than a shield for public good" (internal citations omitted).

Court Allows New York Public Health Law Statutory Claims Against Nursing Home and Its Administrator, in Addition to Traditional Malpractice and Negligence Claims

Morisette v. Terence Cardinal Cooke Health Care Center, 797 N.Y.S.2d 856 (Sup. Ct., New York County, 2005). The Supreme Court, New York County, denied a request by defendant Terence Cardinal Cooke Health Care Center (the "Center") for dismissal of claims against it and its administrator under a state statute that provides a private right of action to nursing home residents injured as a result of a deprivation of any right or benefit conferred by any federal or state law. The Center was sued by the executrix of the estate of a woman in her 80s who resided at the Center for about two weeks. The complaint alleges that the woman died as a result of the Center's failures to properly provide and implement a plan of care and to provide adequate facilities and personnel to care for her. In addition to claims for negligence, medical malpractice, and a lack of informed consent, plaintiff sought relief pursuant to Public Health Law § 2801-d.

PHL § 2801-d provides in relevant part that, "[a]ny residential health care facility that deprives any patient of said facility of any right or benefit, as hereinafter defined, shall be liable to said patient for injuries suffered as a result of said deprivation . . . For purposes of this section a 'right or benefit' of a patient of a

residential health care facility shall mean any right or benefit created or established for the well-being of the patient by the terms of any contract, by any state statute, code, rule or regulation or by any applicable federal statute, code, rule or regulation, where noncompliance by said facility with such statute, code, rule or regulation has not been expressly authorized by the appropriate governmental authority." PHL § 2801-d awards successful litigants compensatory damages and, where the deprivation of the patient's right or benefit is found to have been willful or in reckless disregard of the lawful rights of the patient, punitive damages and attorneys' fees may be awarded.

The Center argued unsuccessfully that PHL § 2801-d does not apply to routine malpractice and negligence claims because otherwise every such case would be converted into a civil rights action. In disagreeing with the Center, the Court noted that, "[t]he legislative history [of PHL § 2801-d] evinces an intent to provide an additional avenue of relief to the vulnerable nursing home population to insure that their rights are enforced . . . The legislative history demonstrates that the Legislature was aware that incentives were needed to induce attorneys to bring suits on behalf of injured patients, so as to deter future deprivations and compensate those who are injured." Accordingly, the Court held that the plaintiff could pursue traditional medical malpractice and other tort claims against the Center simultaneously with claims arising from the patient's rights under PHL § 2801-d.

Further, the Court held that the Center's administrator could be sued under PHL § 2801-d for his alleged failure to ensure that federal and state laws and regulations were implemented and adhered to with respect to the adequacy of the Center's facilities and staffing, and in failing to ensure that adequate plans of care were developed for the Cen-

ter's residents. The Court did, however, dismiss the medical malpractice and lack of informed consent, as plaintiff had presented no evidence that the administrator provided any direct medical care to the patient.

Court of Appeals Finds Seven-Year Delay in Audit of Nursing Home "Untimely"

In re Blossom View Nursing Home v. Antonia C. Novello, M.D., as Commissioner of Health of State of New York, et al., Court of Appeals of New York, April 28, 2005.

Blossom View brought an Article 78 proceeding to bar the New York State Department of Health (DOH) from conducting audits of its patient review instruments (PRIs), because, in this instance, it had been more than six years since the PRIs were filed.

The PRI is used by DOH to determine a nursing home's case mix index (CMI). The amount of care needed by nursing home residents is used to determine the Medicaid reimbursement rate of each facility. The diagnoses of the residents and their functional ability to perform activities of daily living are used in a calculus for determining the CMI, and generally the higher the CMI, the higher the reimbursement. Assessment of residents' condition and functional ability is accomplished through the PRI.

Nursing homes are required to submit new PRIs every six months, with interim updates based on admissions and discharges. DOH uses a three-step audit process to verify the accuracy, and conducted such an audit on Blossom View in August 1993, performing a Step I audit of Blossom's July 1993 PRIs. Because the Step I auditor found statistically different results than Blossom's own evaluation, a Stage II audit was scheduled for December 1993. Again, the auditors results were statistically and significantly different than Blossom's, and the

facility was granted another Stage II audit based on a letter from Blossom's lawyers regarding the manner in which the previous audits had been conducted. Two outside auditors came in March 1994. However, a required 'exit conference' following this third audit was never given and despite Blossom's requests, nothing happened concerning this review for seven years.

After another review of Blossom's 1993 PRIs in 2002, a statistically significant difference was still found, however Blossom was no longer able to question the determinations for about half of the auditors' findings, likely because supporting documentation was no longer available. Blossom was therefore sanctioned by (presumably) lowering its CMI and requiring that it hire independent assessors to perform its next four PRI audits. Despite an appeal to the agency, no relief was granted.

The DOH, in August 2002, informed Blossom of its intention to audit Blossom's 1994 PRIs in November 2002; Blossom refused. When Blossom was given the choice of making medical records available to the auditor, or having all of its functional assessments reduced to their lowest levels, Blossom filed this suit.

The Supreme Court granted Blossom a TRO barring the DOH from auditing PRIs for 1994-1996, and later issued a decision barring such audits and directing DOH to recalculate the Medicaid reimbursement rate from the PRIs as originally filed. The Appellate Division reversed on the law and dismissed the petition.

The Court of Appeals traced the historical shifting of Medicaid-related auditing responsibilities through the Department of Social Services (DSS) to the DOH, for the probable purpose of introducing or explaining the varying sources of regulations governing such audits. The Court

then compared the applicable, and often overlapping, regulations.

Both the DOH's 10 N.Y.C.R.R. 86-2.7 and the DSS's 18 N.Y.C.R.R. 517.3 require fiscal and statistical records and reports used for audits, and the documents underlying such reports, to be kept and maintained by the facility for not less than six years. The DSS's regulations go on to say that, "[a]ll required fiscal and statistical reports are subject to audit for a period of six years from the date of their filing or from the date when such reports were required to be filed, whichever is later" (emphasis added by the Court of Appeals) 18 N.Y.C.R.R. 517.3(a)(2). Also, 18 N.Y.C.R.R. 517.3(c) indicates that "[n]otification by the department to the provider of the department's intent to audit shall toll the six year period for record retention and audit."

The Court paid special attention to the DOH's regulation of PRIs specifically, which section states, in part, "[t]he patient review form (PRI) and any underlying books, records, and/or documentation which formed the basis for the completion of such form shall be subject to review by [DOH]" and "[DOH], in order to ensure accuracy of the [PRI], may also conduct timely onsite observations and/or interviews of patients/residents and review of their medical records" 10 N.Y.C.R.R. 86-2.30[e][5](emphasis added by the Court). Lastly, 10 N.Y.C.R.R. 415.22(b) requires residents' "[c]linical records" to "be retained for six years from the date of discharge or death" (emphasis added by the Court).

Thus, the Court points out that, "six years is indisputably the period for record retention and audit of fiscal and statistical reports and their supporting documentation as well as for the retention of a resident's clinical records after discharge or death." The Court goes on to conclude, however, that because PRIs are neither

"fiscal and statistical records or reports" nor the "underlying books, records and documentation," it does not follow that DOH must audit PRIs within six years of filing.

The standard under which the Court decided the question is one of deference if the interpretation is not irrational. Blossom had argued that the only rational interpretation of the regulations is that 10 N.Y.C.R.R. 86-2.30[e][5] is meant to incorporate the six-year limitation. This is rational, they argued, because otherwise nursing homes would have to deal with PRI audits many years after residents died, staff had left and the rules for completing or auditing PRIs would have changed. The Court finds Blossom's arguments compelling, but regardless the fact that the interpretation is "not . . . the most natural" or "could be interpreted in another way, does not make the interpretation irrational." In re Elcor Health Servs. v. Novello, 100 N.Y.2d 273, 280, 763 N.Y.S.2d 232, 794 N.E.2d 14 (2003).

The Court, however, does not rest there, but shifts its focus away from the six-year limitation to the "timely" requirement of 10 N.Y.C.R.R. 86-2.30[e][5]. On the facts of this case, that is the DOH's desire to audit Blossom's 1994 PRIs more than six years after their filing, and solely because DOH, for nearly nine years, neglected the audit process of Blossom's 1993 PRIs because of an "administrative oversight." The Court held the audit of Blossom's PRIs filed in 1995 and 1996 untimely as a matter of law.

The Court thus ordered the conversion of the litigation to a declaratory judgment, declaring that DOH may not audit or adjust Blossom's CMI for January 1, 1994, through December 31, 1996, therefore the CMI will remain as originally calculated by Blossom's filed PRIs from 1994–1996.

Waiver Provision of Labor Law § 740 Is Irrevocable Upon Commencement of the Action; Waiver Provision Does Not Apply to Bar Federal Causes of Action

Reddington v. Staten Island University Hospital, 373 F.Supp.2d 177 (E.D.N.Y. 2005). In this case, plaintiff, the former manager and coordinator for international patients, sued the defendant Hospital, claiming termination in retaliation for protected activities under federal and state statutes. In her original complaint, plaintiff asserted eight causes of action, including (1) violation of the Age Discrimination in Employment Act; (2) age discrimination in violation of New York Executive Law § 290, et seq.; (3) violation of the New York City Human Rights Law; (4) retaliation pursuant to New York Labor Law § 740; (5) retaliation pursuant to New York Labor Law § 741, New York's whistle-blower statute for health care employees; (6) violation of the Fair Labor Standards Act; (7) intentional infliction of emotional distress; and (8) breach of contract. Before defendant filed its answer, plaintiff filed an amended complaint in which she dropped the Labor Law § 740 claim.

The Court held that the waiver provision of Labor Law § 740 applied despite the fact that plaintiff dropped the Section 740 claim from her amended complaint. Dismissal of the Section 740 claim did not nullify the effect of the waiver provision, even though this took place prior to an answer being filed by defendant. According to the Court, the waiver is triggered upon the commencement of the Section 740 claim. The Court also stated that by instituting the Section 740 claim, plaintiff waived her Labor Law § 741 claim. The Court rejected the Labor Law § 741 claim on the additional ground that only health care workers can claim the protection of its provisions and because plaintiff, as a Coordinator and Manager of Volunteer Services, did not fall within that category.

Notably, the Court further held that a cause of action under Labor Law § 740 does not act as a waiver of federal causes of action because "an effort by New York to condition a state law right on the waiver of arguably unrelated federal rights would raise serious constitutional questions."

Commencement of Labor Law § 740 Action Waives All State Claims Arising Out of the Same Retaliatory Action on Which the § 740 Claim Is Based; Employee Handbook Did Not Give Rise to Breach of Contract Claim

Rohlehr v. Brookdale University Hosp. and Medical Center, 2005 WL 1458714 (E.D.N.Y. 2005). Plaintiff, a former file clerk with the defendant hospital, claimed that he was terminated in retaliation for filing a complaint with the National Labor Relations Board (NLRB) alleging that the hospital had threatened to closely monitor his job performance due to his union activities. He claimed violations of New York Labor Law § 740, termination of employment in violation of the defendant's employee handbook and other related claims.

The Court dismissed the Labor Law claim on the ground that the complaint failed to state, as required, that the defendant hospital violated any law, rule or regulation designed to protect public health or safety, or that the hospital's retaliation against plaintiff posed such a threat. The allegation that plaintiff was retaliated against for asserting his right to engage in union activities did not meet that threshold.

The Court also dismissed plaintiff's claim that the hospital terminated him in violation of the hospital's employee handbook, on the ground that commencement of an action pursuant to Labor Law § 740 constitutes a waiver of any claim based on a collective bargaining agreement or employee contract. (Labor Law §

740(7) states that "institution" of an action under § 740 "shall be deemed a waiver of the rights and remedies available under any other contract, collective bargaining agreement, law, rule or regulation or under the common law.") The Court emphasized that, under § 740(7)'s waiver provision, when a plaintiff commences an action asserting a claim for relief pursuant to § 740, he waives all claims that arise out of the same retaliatory action on which the § 740 claim is based. The Court added that dismissal of the Labor Law § 740 claim did not revive plaintiff's breach of contract claim because dismissal of the § 740 claim "does not negate the § 740(7) waiver."

In any event, the Court found that the employee handbook did not create a contractual right to employment. It stated that to succeed on a breach of contract claim arising from termination in violation of an employee handbook, a plaintiff must show that the employer had an express written policy limiting the right of discharge and that the plaintiff detrimentally relied on that policy in accepting employment. In *Rohlehr*, the employee handbook submitted by the hospital was prefaced with the instruction that it "does not either directly or indirectly constitute an employment contract" and that it is "subject to change at any time," which negated that essential element.

A Cause of Action Under Labor Law § 740 Requires Allegations That the Employee Was Terminated in Retaliation for Reporting an Actual Violation of a Law, Rule, or Regulation; an Employee's Good Faith, Reasonable Belief That a Violation Occurred Is Insufficient

Nadkarni v. North Shore-Long Island Jewish Health System, 799 N.Y.S.2d 574 (2d Dep't 2005). In this case, plaintiff, an employee of the defendants North Shore-Long Island Jewish Health System and Franklin Hospital Medical Center, commenced a "whistle-blower" action pursuant to Labor Law § 741. Plaintiff alleged that the defendants unlawfully terminated her employment because she complained and refused to participate in a proposed plan to use hospital volunteers to assist hospital employees with the service and retrieval of patients' meal trays. According to plaintiff, the plan violated the Health Care Financing Administration Regulation § 483.35, which requires hospitals to provide residents with "nourishing, palatable, and well balanced diets' and to employ sufficient support personnel to carry out the functions of the dietary service.

Labor Law § 741, effective September 9, 2003, prohibits retaliatory action by an employer against a health care employee who discloses or threatens to disclose an activity, policy or practice of the employer that the employee, in good faith, reasonably believes constitutes improper quality of patient care, in that it may present a substantial and specific danger to public health or safety or a significant threat to the health of a specific patient.

The Court dismissed the Section 741 claim for failure to state a claim. The Court also denied plaintiff's request to replead the case as one under Labor Law § 740, for plaintiff's failure to show that she was retaliated against for having reported an actual violation of a law, rule, or regulation. The basis for the decision was that the revised plan was never implemented, and that plaintiff's claim that using volunteers would adversely affect patient health and cause a substantial and specific danger to the public health or safety was no more than speculation. The Court added that the employee's good faith, reasonable belief that a violation occurred was insufficient to please a claim under Section 740.

Hospital Forced to Disclose Material Relating to Patient's Medical Records Despite HIPAA Defense in Connection with Administrative Disciplinary Proceedings Against Nurse

Chapman, R.N. v. Health and Hospitals Corp., Woodhull Medical & Mental Health Center, 796 N.Y.S.2d 881 (Sup. Ct., Kings County 2005). In Chapman, the petitioner, a nurse, sought to compel her previous employer, Health and Hospitals Corp., Woodhull Medical & Mental Health Center, to produce documents in connection with an administrative disciplinary hearing. The hospital employed the petitioner as a registered nurse in its Labor and Delivery Unit. The hospital terminated her employment after it learned of irregularities in the way morphine was administered and handled during petitioner's shifts. She challenged her termination by alleging that she did not engage in misconduct, and that any mishandled medications resulted from conduct by other staff in the Labor and Delivery Unit on the dates in question.

Among other things, the nurse sought a list of names, medical information and the names of treating physicians for all adult female patients and their infants on the date in question. The hospital argued that the Health Insurance Portability and Accountability Act of 1996 (HIPAA)(42 U.S.C. § 1320d-1) prohibited such disclosure, because absent a HIPAA-compliant authorization from the patient, an entity is prohibited from producing any patient records under HIPAA. How-

ever, the statute and its implementing regulations (45 C.F.R. § 160-164) provide for the disclosure of medical records under certain circumstances. Disclosure is permitted in the course of any judicial or administrative proceeding (45 C.F.R. § 164.512(e)). In addition, disclosure may be made in response to an order from a Court or administrative tribunal (45 C.F.R. § 164.512(e)(1)(i)), or in response to a subpoena or discovery request, where the covered entity receives "satisfactory assurance" that the party seeking the information has made reasonable efforts to secure a qualified protective order that meets the requirements of the regulation (45 C.F.R. § 164.512(e)(1)(i)(b)). Finally, when disclosing protected health information, a covered entity must make reasonable efforts to limit such disclosure to the minimum necessary (45 C.F.R. § 164.502(b)).

The Court held that disclosure was permitted under an exception to the statute. Here, the petitioner served a subpoena in connection with an administrative proceeding. However, because the subpoena did not contain the safeguards embodied in a qualified protective order, the Court held that the hospital's failure to respond is defensible. Nonetheless, the Court stated that its decision and order is a qualified protective order that satisfies HIPAA and its regulations, so the hospital must provide the medical records. In its order, the Court stated the hospital is directed to redact the patient names, Social Security numbers, dates of birth, addresses and telephone numbers from the material. The order

also stated that the petitioner is prohibited from using or disclosing the material for any purpose other than the proceeding for which the information was requested, or subsequent proceedings or litigation arising from a determination in the present proceeding, a requirement of a qualified protective order. (*See* 45 C.F.R. § 164.512(e)(1)(v)(A)-(B)).

In a footnote, the Court pointed out that the hospital could have relied on CPLR 3122(a), which provides that a medical provider need not respond to a subpoena *duces tecum* demanding medical records under Article 31 unless accompanied by a written medical authorization by the patient. The hospital here objected only under HIPAA.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a partner in the firm of Garfunkel, Wild & Travis, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg is Chair of the firm's litigation group, and his practice includes advising clients concerning general health care law issues and litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation, contract, administrative and regulatory issues, professional discipline, and directors' and officers' liability claims.

In the New York State Legislature

By James W. Lytle

Unlike most moviegoers, I regard the "coming attractions" portion of the evening to be among the highlights of the movie theater



event, one of the few justifications for actually going to a movie theater. Even the worst movies have scenes that might be entertaining or at least of sufficient interest to retain attention during the three minute "trailer." Taking note of the films I might actually want to see and those I will happily miss seems like a useful exercise, well worth the few moments it adds to the time spent at the theater (or, if applicable, spent for the babysitter.)

Legislative previews may not be quite as entertaining—and may not provide a much better sense of what the "main attraction" actually has to offer, given the vicissitudes of the legislative process and the virtually certain emergence of issues that no one had the prescience to detect on the horizon. With that caveat, here's my sense of the coming legislative session in Albany as it relates to health care legal matters:

Medicaid Reform: Continued concern over the cost of the Medicaid program will surely lead to more calls to address either the breadth of the program or eligibility for its benefits. Still (as of this writing) unresolved federal proposals to curb Medicaid eligibility or to propose further limitations on the transfers of assets on a national basis may also impact on state legislative considerations. During the last session, and at the urging of our colleagues in the New York State Bar Association's Elder Law Section, Martin Golden, Chair of the Senate Aging Committee, advanced a proposal that would

create a "Compact for Long-Term Care." Under this proposal, eligible New Yorkers would either agree to pay for 3 years of nursing home care or pledge 50 percent of their assets and would, after fulfilling that pledge, be entitled to Medicaid coverage for long-term care services. Senator Golden has already signaled that he intends to push this proposal vigorously during the 2006 session.

Medicaid Fraud: As noted last month, the series of exposés in the New York Times led to a flurry of legislative activity, including public hearings, and a blizzard of press releases from various officials and offices involved in Medicaid fraud control. The naming of an Inspector General for Medicaid may be accompanied by consideration of statutory recognition of that office, as well as debate on proposals to restructure the state's approach to Medicaid fraud and overpayment enforcement. Consideration has been given to the concept, for example, of establishing an entity separate from the Health Department to oversee the integrity of the Medicaid payment process and to coordinate fraud and audit responsibilities of all of the affected state agencies in that new entity. Adding to the potential legislative agenda is a potential federal incentive, contained in the Senate version of pending federal Medicaid legislation, that would provide substantial fiscal incentives to states that enact their own false claims and qui tam statutes—an incentive, if enacted by Congress, that New York state may not be able to afford to pass up.

Managed Long-Term Care: Nearly ten years ago, the Legislature authorized a new species of managed care that would be directed at nursing home-eligible people and that would seek to coordinate and cost-effectively manage complex care for its enrollees—at a considerable

savings over their likely fee-for-service expenditures. The statutory authority for managed long-term care programs "sunsets" (or expires) at the end of 2006, which will prompt a review and revision of the program's statutory terms. Hearings were held in November to consider the program's future, including issues relating to its premium structure, the array of services provided under the program, its potential growth and its relationship with other managed care initiatives that have been introduced since the program's inception.

Health Plan Conversion: Last spring, the Court of Appeals upheld the statutory provisions that had permitted the conversion of Empire Blue Cross to a publicly traded entity. As a result of that decision and the acquisition of the newly converted entity by WellPoint, the state stands to benefit from a multi-billion dollar public asset created by the transaction that has been earmarked to support various health care purposes. It is expected that the Legislature will consider whether to broaden the existing conversion legislation to permit more health plan conversions, particularly in light of the proposed conversion of HIP, a longstanding not-for-profit plan—which, just this fall, also announced its intention to merge with GHI, another long-standing not-for-profit health insurer. While the Legislature appears to be generally comfortable with the conversion concept, the more difficult issues relate to how the "public asset" created by the conversion should be utilized.

Commission on Health Care Facilities in the 21st Century: The so-called "Closing Commission," charged with the review of the configuration of the state's health care facilities to meet "the community needs for quality, affordable and

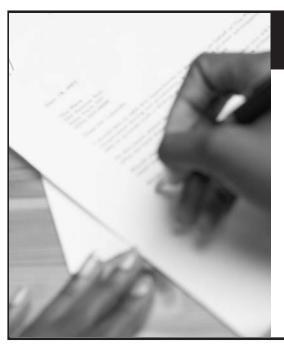
accessible care," will be meeting during the course of the year, along with their regional representatives, to finalize their recommendations to the Governor and the Legislature, due at the end of the year. Those recommendations will include specific suggestions as to "facilities to be closed and facilities to be resized, consolidated, converted or restructured," including the dates that these steps should occur and any investments that should be made to facilitate those steps. The Commission must submit its recommendations to the Governor by December 1, 2006, and those recommendations will be implemented by the Governor unless he fails to submit the report to the Legislature with his approval by December 5 or unless both houses of the Legislature reject the Commission's recommendations in their entirety by December 31. It is, at least as of this writing, far too early

to tell what the prospects are for substantial restructuring of the health care system by the Commission—but December 2006 could prove to be an interesting month.

Disaster Preparedness: Finally, in the aftermath of Hurricane Katrina and continuing concerns over the degree to which the health care system is prepared to deal with bioterrorism, potential pandemics and other natural or man-made disasters, the Legislature has been holding hearings during the off-session on a range of issues that might result in legislative activity in 2006. Although New York state health care facilities are only one part of a comprehensive disaster preparedness strategy, one might expect consideration of proposals that would mandate various training or readiness efforts by hospitals, nursing homes, home care agencies, clinics and health care professionals. The disaster preparedness topic, with a particular focus on the lessons learned from the response of health care facilities in the New Orleans region to the devastation caused by Katrina, will be the focus of our January 25th Annual Meeting program.

I could, of course, provide you with more insight into the upcoming legislative session. But, like a good movie preview, I wouldn't want to dissuade you from actually seeing the show.

Mr. Lytle is a partner in the Albany office of Manatt, Phelps & Phillips, LLP. Mr. Lytle would like to acknowledge the assistance of his colleague from that office, Karen Lipson, with the preparation of this article.



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In the New York State Agencies

By Frank Serbaroli

HEALTH DEPARTMENT

Spousal Impoverishment Budgeting

Notice of continuation. The Department of Health gave notice of its intent to revise § 360-4.10(a)(9) of the Medicaid regulations to clarify that in determining Medicaid eligibility for an institutionalized spouse, a community spouse's pension fund or IRA is a countable resource. *See* N.Y. Register, July 13, 2005.

Nursing Home Pharmacy Regulations

Notice of emergency rulemaking. The Department of Health amended § 415.18(g) and (i) of Title 10 N.Y.C.R.R. to make a wider variety of medications available in nursing home emergency kits and to allow verbal orders from legally authorized practitioners in order to respond quickly to the needs of nursing home residents. Filing date: July 13, 2005. *See* N.Y. Register, August 3, 2005.

Serialized Official New York State Prescription Form

Notice of emergency rulemaking. The Department of Health added Part 910 and amended §§ 85.21, 85.22, 85.23 and 85.25 of Title 10 N.Y.C.R.R. and amended §§ 505.3, 528.1 and 528.2 of Title 18 N.Y.C.R.R. to enact an official New York state prescription form to deter fraud by curtailing theft or copying of prescriptions by individuals engaged in drug diversion. The regulations also define the requirements for using the official prescription form and provide for an 18-month period where both existing prescription forms and the official prescription forms can be used to allow for a transitional period for practitioners, institutions and pharmacists. Filing date: July 21,



2005. Effective date: July 21, 2005. *See* N.Y. Register, August 10, 2005.

Laboratory Confirmed Influenza

Notice of emergency rulemaking. The Department of Health amended § 2.1 of Title 10 N.Y.C.R.R. to add laboratory confirmed influenza to the communicable disease reporting list to enable the Department of Health to have more comprehensive and complete information on influenza cases and permit the state and local health departments to channel limited vaccines, anti-viral agents and public health resources to those in greatest need during an influenza outbreak. Filing date: July 29, 2005. Effective date: July 29, 2005. See N.Y. Register, August 17, 2005.

Adult Care Facility Inspection Reports

Notice of continuation. The Department of Health gave notice of its intent to amend inconsistent provisions of § 486.2(i)(1) of Title 18 N.Y.C.R.R. to require the Department's inspection reports to determine whether each area of operation of an adult care facility is in compliance with regulations. *See* N.Y. Register, August 24, 2005.

Newborn Screening

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend §§ 69-1.1, 69-1.2 and 69-1.3 of Title 10 N.Y.C.R.R. to add thirty-three inherited metabolic disorders to the current New York state newborn screening test panel. *See* N.Y. Register, August 24, 2005.

Part-Time Clinics

Notice of emergency rulemaking. The Department of Health amended §§ 703.6 and 710.1 of Title 10 N.Y.C.R.R. to clarify and enhance the requirements that apply to parttime clinics and require prior limited review of all part-time clinic sites in order to ensure the provision of quality health care to underserved populations through preventive health screening programs and other public health initiatives. Filing date: August 12, 2005. *See* N.Y. Register, August 31, 2005.

Perinatal Regionalization

Notice of adoption. The Department of Health amended §§ 405.21, 407.14, 708.2, 708.5 and 711.4 and added Part 721 to Title 10 N.Y.C.R.R. to update existing requirements for maternal and newborn care and consolidate standards for perinatal regionalization, which are currently divided among several sections of the New York State Hospital Code. Filing date: August 24, 2005. Effective date: September 14, 2005. See N.Y. Register, September 14, 2005.

Health Provider Network Access and Reporting Requirements for Articles 28, 36 and 40 Facilities

Notice of emergency rulemaking. The Department of Health amended §§ 400.10, 763.11, 766.9 and 793.1 of Title 10 N.Y.C.R.R. to require article 28 facilities (hospitals), article 36 facilities (home care agencies) and article 40 facilities (hospices) to establish and maintain health provider network accounts with the Department of Health for the purpose of exchanging information with the Department in a rapid, efficient manner in times of emergency or urgent matters. Filing date: September 9, 2005. Effective date: September

9, 2005. *See* N.Y. Register, September 28, 2005.

Health Provider Network Access and Reporting Requirements

Notice of emergency rulemaking. The Department of Health amended §§ 487.12, 488.12 and 490.12 of Title 18 N.Y.C.R.R. to require adult homes, enriched housing programs and residences for adults to establish and maintain health provider network accounts with the Department of Health for the purpose of exchanging information with the Department in a rapid, efficient manner in times of emergencies or urgent matters. Filing date: September 9, 2005. Effective date: September 9, 2005. See N.Y. Register, September 28, 2005.

Long-Term Ventilator Beds

Notice of adoption. The Department of Health added § 709.17 to Title 10 N.Y.C.R.R. to promulgate a need methodology for long-term ventilator beds in residential health care facilities, which will be utilized to evaluate certificate of need applications and ensure that an adequate number of long-term ventilator beds are available to provide access to care and avoid the unnecessary duplication of resources. Filing date: September 20, 2005. Effective date: October 5, 2005. See N.Y. Register, October 5, 2005.

Adult Care Facility Regulations

Notice of proposed rulemaking. The Department of Health gave

notice of its intent to amend §§ 486.4, 493.2 and 493.8 of Title 18 N.Y.C.R.R. to conform with the Social Services Law, which allows for an adult care facility operating certificate to be suspended or limited without a hearing for a maximum of 60 days. *See* N.Y. Register, October 5, 2005.

INSURANCE DEPARTMENT

Rules Governing Individual and Group Accident and Health Insurance Reserves

Notice of emergency rulemaking. The Department of Insurance repealed Part 94 and added a new Part 94 (Regulation 56) to Title 11 N.Y.C.R.R. to prescribe rules and regulations for the valuation of minimum individual and group accident and health insurance reserves including standards for valuing certain accident and health benefits in life insurance policies and annuity contracts. Filing date: July 15, 2005. Effective date: July 15, 2005. See N.Y. Register, August 3, 2005.

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

Notice of adoption. The Department of Insurance amended Part 52 (Regulation 62) of Title 11 N.Y.C.R.R. to revise the minimum standards for the form, content and sale of Medicare supplemental insurance as a result of changes to the federal minimum standards for Medicare supplemental insurance enacted by the Medicare Prescription Drug, Improvement and Modernization

Act of 2003. Filing date: August 23, 2005. Effective date: September 7, 2005. *See* N.Y. Register, September 7, 2005.

Healthy New York Program

Notice of emergency rulemaking. The Department of Insurance added § 362-2.7 and amended §§ 362-2.5, 362-3.2, 362-4.1, 362-4.2, 362-4.3, 362-5.1, 362-5.2, 362-5.3, and 362-5.5 of Title 11 N.Y.C.R.R. in order to increase the insurance coverage of uninsured workers employed by small businesses, by reducing cost, lessening complexity, and adding a second benefit package to the Healthy New York Program. Filing date: September 1, 2005. *See* N.Y. Register, September 21, 2005.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a partner in Cadwalader, Wickersham & Taft LLP's 18-attorney health law department. He is the Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the New York Law Journal, and serves on the Executive Committee of the New York State Bar Association's Health Law Section. He is the author of *The Corpo*rate Practice of Medicine Prohibition in the Modern Era of Health Care, published by BNA as part of its Business and Health Portfolio Series. The assistance of Vimala Devassy and Jared L. Facher of Cadwalader, Wickersham & Taft LLP, in compiling this summary is gratefully acknowledged.

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In the Journals

American Journal of Law & Medicine Vol 31, No. 1 (2005) (Am. Society of Law, Medicine & Ethics)

- Defining a Standard of Care in the Practice of Acupuncture, Christine C. Kung
- Ethical and Legal Aspects of Using an Identical Twin as a Skin Transplant Donor for a Severely Burned Minor, Samuel J. Tilden
- Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany and Japan, Angela Campbell
- Face Value: Challenges of Transplant Technology, Rhonda Gay Hartman

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Symposium: Health Care Tax
 Exemption: The Push and Pull of
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 Care Services

- Introduction, Laura B.
 Chisolm
- The Impact of Federal Tax
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- The Failure of Community Benefit, John D. Colombo
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 L. (Lorry) Spitzer
- Health Care Joint Ventures
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- Do Fiduciary Duties Contained in Federal Tax Laws
 Effectively Promote National
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- Creating Human Embryos for Research: A Scientist's Perspective on Managing the Legal and Ethical Issues, Emilie W. Clemmens
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- Prenatal Testing Gone Awry: The Birth of a Conflict of Ethics and Liability, Elizabeth A. Ackmann
- A Chimera in Every Sense: Standard of Care for Physicians Practicing Complementary and Alternative Medicine, J. Brad Kallmyer

- Understanding the Disparity in Availability of Prescription Drugs in the United States: Compromise May Be the Answer, Natalie J. Tanner
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- Harnessing the Benefits of Biobanks, Lori B. Andres
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- Should Liability Play a Role in Social Control of Biobanks?, Larry I. Palmer
- Genetic Information, Privacy and Insolvency, Edward J. Janger
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- The 80-Hour Work Week: Why Safer Patient Care Will Mean More Health Care Is Provided by Physician Extenders, Thomas R. McLean
- Silencing the Hired Guns: Ensuring Honesty in Medical Expert Testimony through State Legislation, Juan Carlos B. Gomez
- Refusal Clauses and the Weldon Amendment: Inherently Unconstitutional and a Dangerous Precedent, Jason Green

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- The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, Catherine T. Struve, J.D.
- Symposium: Pharmaceutical Innovation and Cost: An American Dilemma
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 - The Problem of New Uses,
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 - Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex, Richard A. Epstein, LL.B.
 - The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids, Marshall H. Chin, M.D., M.P.H.
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For Your Information

By Claudia O. Torrey

"What Happened?" "How Could This Happen?" "Lessons Learned"; "Building Bridges!" These phrases are examples of what was echoed after Hurricane Katrina decimated the Gulf Coast in August 2005—one of the worst natural disasters our country has ever seen. Arguably, even the best plan is useless if executed too late;1 however, the overwhelming public opinion that prevailed as to the Katrina public health preparedness could be summed up as "the Katrina response was not a failure of government; it was a failure of bad government."2

"A hurricane is essentially an engine that runs on heat The warmer the sea-surface temperature [it must be at least 80° F for a hurricane to start] and the more warm, moist air that's available, the stronger a hurricane can become."3 Through hurricanes Katrina, Rita, Stan, Wilma, Alpha, and Beta, as well as the devastating earthquake in Pakistan, the world realized firsthand the importance of an effective medical response in mitigating catastrophes. Perhaps these natural disasters occurred for "such a time as this."4 "Any response to a disaster is not just a medical response, but is instead a combination of many factors including logistics, management, training, transportation, security, etc. To respond effectively, it is necessary that all of the factors be considered systematically, not as a variety of isolated bits and pieces; such an important system must be tightly structured and staffed at least in greater proportion by professionals, and not relegated solely to a volunteer based organization."5

To its credit, the United States House of Representatives' Subcommittee on Water Resources and Environment invited an expert from the Netherlands to come to a hearing in

order to share his expertise on his country's co-existence with water.6 Mr. Hoogland, the Netherlands expert, stated that almost 60 percent of his country is threatened by water-either by storm surges, and/or by floods due to high discharges of rivers. Noting that his department, Rijkswaterstaat, was comparable to the U.S. Army Corps of Engineers, Mr. Hoogland further stated that over the past 50 years, the Netherlands has invested approximately \$15 billion (in today's costs) in their current Deltaplan. While not an inconsequential cost, nevertheless it is a cost that was deemed pennies on the dollar compared to costs that would have been incurred without such a financial commitment.7 Mr. Hoogland emphasized that the Netherlands protection policy consists of four components: know-how and organizational structure, standards and legislation, priorities and budget, and prevention and zoning.

Some of the recent debates regarding public health emergencies concern whether or not state governments are the controlling entity supervising a "total government response." These debates usually include a discussion of the Commerce Clause, and Congress' alleged ability to act or not act in public health emergencies; a look at the Model State Emergency Health Powers Act;8 and the Department of Homeland Security's National Response Plan—designed to respond to public health emergencies and necessarily override conflicting state actions.9 The debates will continue because Katrina elicited a clarion call, especially regarding "vulnerable populations: the elderly, the homebound, the physically and mentally disabled, those who can't walk, can't drive, can't fend for themselves."10 "We can't ignore what happened and continue on without making sure we

have done everything we possibly can to minimize the loss of life and human suffering We just have to do that."¹¹

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Claudia O. Torrey, Esq. is a member of several professional organizations, including a Sustaining Member of the New York State Bar Association.

Public Health Law § 2801-d and the Nursing Home Crisis: The Propriety of Invoking the Statute in Routine Negligence Cases

By Andrew L. Zwerling

The nursing home industry is plagued by a crisis of immense proportions due, in part, to the increasing practice of plaintiffs, in routine negligence cases, asserting claims based on "residents' rights" statutes, such as New York's Public Health Law (PHL) § 2801-d. Public Health Law § 2801-d was designed to provide nursing home residents with a means by which to enforce their statutory and regulatory rights as residents, by endowing them with a private right of action for damages and other relief stemming from a deprivation of those rights. Unfortunately, however, this salutary statute, and others like it, have been transformed into a vehicle that has helped spawn one of the fastest-growing areas of health care litigation, i.e., lawsuits against nursing homes.

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The ability of plaintiffs in routine negligence cases to use a statutory claim as the basis upon which to parade evidence of alleged regulatory violations before the jury has led to larger jury awards. Fear that juries will confuse evidence of regulatory violations as conclusive proof of negligence has compelled nursing homes to settle otherwise defensible cases or to agree to higher settlements. This has contributed to spiraling insurance and litigation costs that have threatened the viability of nursing homes nationwide.

This article will address the propriety of plaintiffs asserting a statutory claim simultaneously with a negligence claim, where both causes of action are predicated upon the same facts. It is this author's view that PHL § 2801-d was not designed to create a remedy for nursing home residents where there is a viable alternative cause of action, such as a negligence claim, to address the

facts giving rise to the claimed injury. Under such circumstances, negligence and statutory claims may not be pursued together. The statute was designed to supplement existing remedies by providing residents a private right of action where 1) no effective right existed previously and 2) where the alleged injury is *de minimis* and the private bar needs the financial incentives offered by the statute to protect the needs of the resident. In the latter circumstance, a plaintiff must make an election of remedies between pursuing the statutory claim and the traditional tort remedy.

The Statute

In relevant part, § 2801-d(1) of the Public Health Law provides:¹

Any residential health care facility that deprives any patient of said facility of any right or benefit, as hereinafter defined, shall be liable to said patient for injuries suffered as a result of said deprivation, except as hereinafter provided. For purposes of this section a "right or benefit" of a patient of a residential health care facility shall mean any right or benefit created or established for the well-being of the patient by the terms of any contract, by any state statute, code, rule or regulation or by any applicable federal statute, code, rule or regulation, where noncompliance by said facility with such statute, code, rule or regulation has not been expressly authorized by the appropriate governmental authority. No person who pleads and proves, as an affirmative defense, that the facility exercised all care reasonably necessary to prevent and limit the deprivation and injury for which liability is asserted shall be liable under this section.

The statute was part of a larger set of nursing home reforms implemented by the Legislature following revelations of horrifying nursing home abuses in the 1970s.²

Public Health Law § 2801-d was designed to assist residents by providing them with a private cause of action to enforce their statutory rights as residents, as delineated in PHL § 2803-c. Where a resident has "been deprived a right or benefit" and has been injured as a result of that deprivation, PHL § 2801-d provides for: 1) compensatory damages "in an amount sufficient to compensate said patient for such injury," with "minimum damages" fixed at 25% of the "daily per-patient rate of payment" established for the facility; 3 2) an award of attorneys' fees; 4 and 3) punitive damages where the deprivation "is found to have been willful or in reckless disregard of the lawful rights of the resident." 5 The statute also authorizes class action lawsuits. 6

Relevant Case Law: A Need for Clarity

Lower court cases in the Appellate Division, Second Department, have expressly held that where a resident has an available malpractice or negligence cause of action against a nursing home, he or she cannot sue under PHL § 2801-d based upon the same facts. These decisions hold that PHL § 2801-d "was not intended by the legislature to provide a remedy for mere negligence on the part of a residential health care facility, at least where the injured patient has a viable cause of action under principles of tort liability."

In Begandy v. Richardson, a patient slipped and fell down stairs at a nursing home and, after filing suit, attempted to amend the complaint to add a claim under Public Health § 2801-d. Relying on the statute's legislative history, the court denied the plaintiff's application, holding that the resident had no cause of action under the statute, because the statute does not apply where a resident has a pre-existing right to bring a negligence action against the nursing home. The court also noted that additional statutory provisions, such as the inclusion of minimum damages and the right to bring class actions, were "not indicative of a typical personal injury action," and thus, further supported the conclusion that the statute was not intended to be used in a negligence action.¹⁰ The court also opined that the Legislature could not have intended for plaintiffs alleging negligence to use PHL § 2801-d to "alter the traditional burden of proof . . . in a negligence action" by requiring defendant-nursing homes to plead and prove that it exercised reasonable care to avoid liability.11

In *Bielewicz v. Maplewood Nursing Home, Inc.,*¹² the court held that PHL § 2801-d did not create a private right of action for a nursing home resident who, left unattended, fell from his wheelchair. As the court stat-

ed, the statute is "not meant to authorize a private cause of action in every negligence case." Similarly, in *Irma Acevedo v. Augustana Lutheran Home*, the court denied plaintiffs' motion to amend the complaint to add a statutory claim under PHL § 2801-d, stating that it was "not prepared to find that a separate cause of action exists under Public Health Law § 2801-d."

In *Goldberg v. Plaza Nursing Home*, ¹⁵ the Appellate Division, Fourth Department, adopted the reasoning of the court in *Begandy v. Richardson, supra*, in rejecting an attempt by the administratrix of an estate to sue under the Public Health Law, where that cause of action was based upon the same facts as claims for wrongful death and intentional and negligent infliction of emotional distress. As the Fourth Department stated: ¹⁶

The record establishes that plaintiff's fourth cause of action is predicated on defendant's negligence. The various memoranda that accompanied the enactment of Public Health Law § 2801-d show that the purpose of that section was to provide a remedy to patients in residential health care facilities who are denied the rights and benefits enumerated in Public Health Law § 2801-c(3); the purpose of the statute was not to create a new personal injury cause of action based on negligence when that remedy already existed (see, 1976 McKinney's Session Laws of N.Y., at 1685–1686, 1764).

. . .

[W]e conclude that it is unlikely that the Legislature envisioned extension of the principle of strict liability to residential health care facilities for injuries and damages that are traditionally the subject of tort liability.

There are Appellate Division cases seemingly to the contrary, but, upon close scrutiny, those decisions do not clearly stand for the proposition that statutory claims may be pursued together with negligence claims even when based upon the same facts.¹⁷

In *Doe v. Westfall Health Care Center*, ¹⁸ the mother of an incapacitated nursing home resident brought an action against a skilled nursing home alleging negligence and a Public Health Law violation based upon the rape of her daughter by a nursing home's male health care aide. In sustaining the claim under § 2801-d,

the Appellate Division, Fourth Department, expressly declined to apply its reasoning in Goldberg v. Plaza Nursing Home, supra. The Fourth Department stated that, "[i]n our case, the complained-of conduct here—the rape of plaintiff's decedent—is precisely the sort of conduct that the Public Health Law section at issue was designed to target," because "recovery for such conduct is often barred for plaintiffs who sue at common law . . . Suits against hospitals or nursing homes to recover damages arising from sexual assaults upon patients usually founder because of the absence of the requisite element of foreseeability, i.e., the facility's lack of prior knowledge of the perpetrator's criminal tendencies."19 "On this set of facts," and because of the "inadequacy of the common law causes of action" to redress this type of abuse, the Fourth Department sustained the plaintiff's § 2801-d claim. The Fourth Department overruled Goldberg v. Plaza Nursing Home, supra, only to the extent it mandated summary judgment of the Public Health Law claim where the viability of a co-existing common law cause of action was in doubt and a plaintiff would have no remaining right of action.²⁰

But, as noted in the Second Department case of Bielewicz v. Maplewood Nursing Home, supra, the holding in *Doe v. Westfall Health Care Center, supra,* is limited to those instances where there is a "difficulty of recovery under common law." The Doe "exception was not meant to authorize a private cause of action in every negligence case."21 Moreover, in Doe v. Westfall Health Care Center, supra, the plaintiff's negligence claim was one for negligent hiring and was not based upon the same facts as the PHL § 2801-d claim. Rather, the statutory claim was based upon a resident's right to be free from mental and physical abuse under PHL § 2803c[3][h]. Thus, the court in *Doe v. Westfall Health Care* Center, supra, did not address a scenario in which the statutory and common-law claims depended upon the same facts.

In Zeides v. Hebrew Home For the Aged,²² the Appellate Division, First Department, declined to dismiss the plaintiff's PHL § 2801-d claim in a negligence action. The First Department noted, however, that the sole issue before it was the timeliness of the plaintiff's medical malpractice claim.²³ Although the First Department stated that plaintiffs therein stated a cognizable action under the statute, it is notable that the defendant nursing home did not even acknowledge, address or attack the viability of the statutory cause of action.²⁴ Significantly, in his dissenting opinion, Justice Friedman, referencing Goldberg and Begandy, supra, acknowledged that "the purpose of section 2801-d was 'not to create a new personal injury cause of action based on negli-

gence when that remedy already existed," and took issue with the majority's finding of a statutory claim where the issue was not even addressed by the parties.

Finally, in Fleming v. Barnwell Nursing Home and Health Facilities,²⁵ the Third Department upheld a plaintiff's right to amend a medical malpractice complaint by adding a claim under PHL § 2801-d. However, the issue of whether a plaintiff can simultaneously seek recovery for negligence and under § 2801-d, based on the same harm, was neither raised before or addressed by the court.

The Legislative History Favors the View that Plaintiffs Should Not Be Permitted to File Public Health Law Claims Based Upon the Same Facts As a Negligence Claim

It is firmly settled that "[t]he primary consideration of the courts in the construction of statutes is to ascertain and give effect to the intention of the Legislature." Legislative intent drives judicial interpretations in matters of statutory construction. PHL § 2801-d supports the position that the statute does not authorize simultaneous assertion of a statutory claim and a negligence claim based on the same facts.

Memoranda underlying the enactment of PHL § 2801-d show "that the purpose of 2801-d was to create a private right of action where no such right previously existed." Obviously, the right of a nursing home resident to bring a personal injury action predicated on the nursing home's negligence existed prior to the passage of 2801-d." Thus, restricting a resident who has filed a malpractice lawsuit from asserting a statutory claim based upon the same facts underlying the malpractice claim is consistent with and in no way thwarts the legislative purpose behind enactment of PHL § 2801-d.

PHL § 2801-d was also designed to provide residents with a means by which to enforce their rights as residents where existing law failed to provide an *effective* remedy. In support of the bill, proponents argued that, although nursing home residents had a right to sue under common law theories of liability, the elderly population was vulnerable and often lacked the monetary resources to fund a lawsuit. The bill's sponsors sought to provide an incentive to "increase the willingness of patients and the legal profession" to file lawsuits by providing a specific statutory right of action, Medicaid-exempt minimum damage awards, and—significantly—the right to bring class action suits and recover attorneys' fees. The goal was to increase "the potential recovery in a lawsuit . . . large enough to

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encourage the private bar to bring suits on behalf of nursing home patients."³²

Denying a resident the ability to pursue a statutory claim based on the same facts as a negligence cause of action does not undermine this legislative goal. Where a resident has a viable negligence or malpractice claim, the availability of a contingency fee arrangement eliminates concerns about a resident's lack of financial resources and provides incentive for attorneys to take on such cases.³³ Under such circumstances, the financial incentives offered by the statute are unnecessary, yet the statutory objective—ensuring that a resident has a viable means by which to pursue a claim—is satisfied. It is only where a resident does not have a pre-existing common law claim or where the alleged injury is de minimis that the statutory incentives are needed and helpful. Under those circumstances, restricting a resident to purely a statutory claim, with its built-in financial incentives, and compelling the resident to forgo the negligence or malpractice claim, in no way diminishes the efficacy of those incentives or undermines the goal of the statute.

Unintended Implications: Shifting the Burden of Proof and the Award of Attorneys' Fees

Permitting a nursing home resident to pursue a statutory claim based upon the same facts as a malpractice or negligence claim effectively shifts the burden of proof in negligence cases from plaintiffs to defendants. This shift, however, runs contrary to fundamental New York law, which places the burden of proving negligence squarely on plaintiffs.

It is fundamental that in a negligence case the plaintiff bears the burden of establishing a breach of duty on the part of the defendant.³⁴ Also, where a negligence claim is based on the violation of an agency regulation, that transgression merely constitutes "some evidence" of negligence, and is not conclusive of the issue as a matter of law.³⁵

By contrast, under PHL § 2801-d, a patient need only prove a deprivation by a residential health care facility of "any right or benefit created or established for the well-being of the patient by the terms of any contract, by any state statute, code, rule or regulation or by any applicable federal statute, code, rule or regulation" (and a causal link between that deprivation and an injury to the patient). At that juncture, the burden shifts to the facility to prove, as an affirmative defense, that it "exercised all care reasonably necessary to prevent and limit the deprivation and injury for which liability is asserted . . ."³⁶

Therefore, if a resident is permitted to assert a statutory claim based upon the same facts as a negligence claim and meet his burden of proof upon a mere showing of a violation by the facility of an agency rule or even a contract, in ordinary negligence cases the burden of proof would be shifted to defendants to establish, as an affirmative defense, that they complied with the standard of care. This "would significantly alter the traditional burden of proof requirements in a negligence action whenever injury is suffered by a patient in a health care facility . . . It is doubtful that this is what the legislature intended."³⁷ In the absence of a clear legislative intent to alter existing common law negligence principles, an interpretation of PHL § 2801-d that would permit such a result must be rejected.³⁸

Permitting plaintiffs to assert a statutory claim based upon the same facts as an ordinary negligence claim would give rise to other implications that could not have been intended by the Legislature. For example, although attorneys' fees are not recoverable in negligence actions, they are authorized under PHL § 2801-d(6). Thus, in a routine negligence case, a resident can seek otherwise unobtainable attorneys' fees merely be advancing a statutory claim based on the same facts.

Significant Public Policy Considerations

Permitting plaintiffs to pursue statutory claims under PHL § 2801-d based upon the same facts as their negligence claims gives rise to public policy implications that justify proscribing such an approach.

Invocation of a Public Health Law claim in a negligence action enhances the possibility of a nursing home settling an otherwise defensible case or of an adverse jury verdict. In a negligence action where a Public Health Law claim is simultaneously pursued based upon the same facts, a plaintiff will attempt to introduce evidence of regulatory violations under the guise that such evidence is properly admitted in support of their statutory claim. This gives rise to the genuine likelihood that juries will confuse evidence of regulatory violations, no matter how trivial, with proof of negligence and unfairly conclude that a nursing home guilty of regulatory violations must be negligently run.³⁹ Not only does this dynamic increase the possibility of larger jury verdicts, but also, faced with this possible evidentiary confusion by juries, nursing homes have settled cases that were otherwise defensible and have paid higher settlements.⁴⁰ This, in turn, has led to enhanced litigation costs and insurance premiums and further strain on the limited resources of nursing homes. It also threatens the ability of nursing homes to maintain operations and provide adequate care to their residents.

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As it is, due to strong patients' rights statutes, nursing homes have become the "new target of litigation" throughout the country.⁴¹ Not only has there been dramatic increases in the number of lawsuits instituted, there has also been a tremendous increase in the size of awards. 42 As detailed in numerous reports and articles, this exponential surge in litigation has given rise to an insurance crisis that is plaguing the nursing home industry. Malpractice coverage has skyrocketed and the liability cost per bed has also increased. 43 In response to increased malpractice and litigation costs, many nursing homes have reduced or eliminated their liability insurance and some have even abandoned their operations.44 The result has been to leave some residents without any care.⁴⁵ An overly expansive interpretation of PHL § 2801-d exacerbates this crisis.

Other costs are implicated where a plaintiff is permitted to assert a statutory claim with an ordinary negligence claim. The scope of discovery is rendered susceptible to fishing expeditions by plaintiffs looking for proof of any and all regulatory violations that may support the statutory claim. The scope of discovery in a negligence case can be easily distorted from the narrower inquiry of whether a duty toward a resident has been breached to whether the facility is guilty of any regulatory violations in any facet of its operations. Responding to such broad discovery gives rise to a time consuming and costly disruption of the day-to-day operation of a facility. These are the very dangers anticipated by various opponents of Bill No. S-6551, which was enacted as Public Health Law § 2801-d. The Federation of Protestant Welfare Agencies, Inc., wrote to the Senate and predicted that the Bill[] "open[s] the door to the possibility of numerous nuisance suits which, though ultimately dropped or found to be unfounded, would put the agency [and other not-for-profit and forprofit nursing homes] in jeopardy vis a vis its financial security, reputation, and smooth administration."46

Conclusion

It is doubtful that the Legislature, in seeking to protect vulnerable nursing home residents, intended to swing the pendulum so far and to jeopardize the survival of the nursing home facilities, which is a conceivable consequence of allowing residents to assert statutory and negligence claims based upon the same facts. It may well be that only the Legislature can resolve this debate, perhaps with a statutory amendment that requires an election of remedies by a resident. Until the statute is amended and clarified, however, this dispute will persist, with varying results depending upon the view of the individual judge hearing the case.

Endnotes

- 1. N.Y. Public Health Law § 2801-d(1).
- Morisett v. Terence Cardinal Cooke Health Care Center, 8 Misc.3d 506, 509–510, 797 N.Y.S.2d 856 (Sup. Ct., N.Y. Co. 2005).
- 3. PHL § 2801-d(2).
- 4. PHL § 2801-d(6).
- 5. PHL § 2801-d(2).
- 6. PHL § 2801-d(4).
- 7. See also Young v. A. Holly Patterson Geriatric Center, 17 A.D.3d 667, 792 N.Y.S.2d 914 (2d Dep't 2005) (in action to recover damages for medical malpractice, court denied motion to amend to add PHL § 2801-d claim).
- 8. See 65 N.Y. Jur.2d Hospitals, § 45.
- 9. 134 Misc.2d 357, 510 N.Y.S.2d 984 (Sup. Ct., Monroe Co. 1987).
- 10. Id.
- 11. Id. at 360, 510 N.Y.S.2d at 986.
- 12. 4 Misc.3d 475, 778 N.Y.S.2d 666 (Sup. Ct., Monroe Co. 2004).
- 13. 778 N.Y.S.2d at 669.
- 14. 2004 WL 3261175 (Sup. Ct., Kings County).
- 15. 222 A.D.2d 1082, 635 N.Y.S.2d 841 (4th Dep't 1995).
- 16. 222 A.D.2d at 1084, 635 N.Y.S.2d at 842.
- 17. But see Morisett v. Terence Cardinal Cooke Health Care Center, 8
 Misc.3d 506, 797 N.Y.S.2d 856 (Sup. Ct., N.Y. Co. 2005) (comprehensive decision by Justice Sklar in which he permitted statutory claim to be brought with negligence and lack of informed consent claims). See also Spakoski v. Amsterdam Memorial Hospital Skilled Nursing Facility, 6 Misc.3d 757, 789 N.Y.S.2d 408 (Sup. Ct., Montgomery County 2005) (court suggested that statutory claim may be brought in action for personal injuries suffered by resident in a fall); Barnes v. Lawrence Nursing Care Center, 2 Misc.3d 337, 773 N.Y.S.2d 208 (Sup. Ct., Kings Co. 2003) (claim for damages for conscious pain and suffering was predicated, in part, on alleged violation of PHL § 2801-d).
- 18. 303 A.D.2d 102, 755 N.Y.S.2d 769 (4th Dep't 2002).
- 19. Id. at 110, 755 N.Y.S.2d at 775.
- 20. 775 N.Y.S.2d at 776.
- 21. 778 N.Y.S.2d at 669 (the Fourth Department in *Doe* "did not overrule Goldberg").
- 22. 300 A.D.2d 178, 753 N.Y.S.2d 450 (1st Dep't 2002).
- 23. See id. at 179, 753 N.Y.S.2d at 452.
- 24. Id.
- 25. 309 A.D.2d 1132, 766 N.Y.S.2d 241 (3d Dep't 2003).
- 26. People v. Santi, 3 N.Y.3d 234, 243, 785 N.Y.S.2d 405 (2004).
- 27. People v. Allen, 92 N.Y.2d 378, 383, 681 N.Y.S.2d 216 (1998).
- Begandy v. Richardson, 134 Misc.2d 357, 361, 510 N.Y.S.2d 984 (Sup. Ct., Monroe Co. 1987).
- 29. 510 N.Y.S.2d at 986.
- See Begandy v. Richardson, 134 Misc.2d 357, 510 N.Y.S.2d 984 (Sup. Ct., Monroe Co. 1987).
- 31. See 1975 Senate Rep. No. 6551-B; Memo of State Executive Department, reprinted in 1975 McKinney's Session Laws of New York, at 1685–1686. See also Daniel M. Gitner, Nursing the Problem: Responding to Patient Abuse in New York State, 28 COLUM J. L & SOC. PROBS. 559, 597–599 (1995) ("These provi-

- sions help overcome tort law's inadequacy in dealing with nursing home patient abuse" by "allowing for a minimum recover, attorney's fees, class actions, punitive damages, and the possibility of suing the nursing home.").
- 32. 1975 Senate Rep. No. 6551-B, at 1, par.2 ("Summary of Provisions); Begandy v. Richardson, 134 Misc.2d 357, 360–361, 510 N.Y.S.2d 984 (Sup. Ct., Monroe Co. 1987). See also Jacobs v. Newton, 1 Misc.3d 171, 181, 768 N.Y.S.2d 94 (Civil Ct., Kings Co. 2003) ("clear intent of [this statute] was to expand the existing remedies for conduct that, although constituting grievous and actionable violation of important rights, did not give rise to damages of sufficient monetary value to justify litigation").
- See Begandy v. Richardson, 134 Misc.2d 357, 361, 510 N.Y.S.2d 984 (Sup. Ct., Monroe Co. 1987).
- See Derdiarian v. Felix Constr. Corp., 51 N.Y.2d 308, 314–315, 434
 N.Y.S.2d 166 (1980); La Fountain by La Fountain v. County of Clinton, 237 A.D.2d 808, 654 N.Y.S.2d 870 (3d Dep't 1997).
- Long v. Forest-Fehlhaber, 55 N.Y.2d 154, 160, 448 N.Y.S.2d 132 (1982).
- 36. PHL § 2801-d(1).
- Begandy v. Richardson, 134 Misc.2d 357, 510 N.Y.S.2d 984, 985–986
 (Sup. Ct., Monroe Co. 1987).
- See Seligman v. Friedlander, 199 N.Y. 373, 376, 92 N.E. 1047 (1910), cited in Lurene F. v. Olsson, 190 Misc.2d 642, 645, 740 N.Y.S.2d 797 (Sup. Ct., Broome Co. 2002).
- See "Diagnosing the Nursing Home Liability Insurance Crisis, A Case for Reforming the System," William J. Warfel, CPCU Society (Jan. 2003 Newsletter).
- 40. Id
- See R. Patrick Bedell, The Next Frontier in Tort Reform: Promoting the Financial Solvency of Nursing Homes, 11 ELDER L.J. 361 (2003), at 371.
- 42. See study issued on July 25, 2002 by the United States Department of Health and Human Services, entitled, "Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs by Fixing Our Medical Liability System."
- See also R. Patrick Bedell, The Next Frontier in Tort Reform: Promoting the Financial Solvency of Nursing Homes, 11 ELDER L.J. 361 (2003), at 369–374.
- 44. Id
- 45. *Id. See also* "Nursing Home Liability Insurance Crisis," Richard S. Biondi, August 10, 2005 (www.milliman.com).
- See Memo. of Fed. of Protestant Welfare Agencies, Inc., dated June 23, 1975.

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The Use of Pre-Dispute Arbitration Clauses in New York Nursing Home Agreements

By Jane Bello Burke

Introduction

It has long been the accepted rule in New York that nursing homes cannot include pre-dispute arbitration clauses in their admission agreements with residents. In an arbitration clause, the parties agree in advance to submit any future claim or controversy between them to binding arbitration. The practical import of the provision is to forgo the right to commence an action in court and to waive the right to a trial by jury.

This conventional wisdom reflects an ancient hostility—albeit one rapidly losing ground—disfavoring predispute arbitration agreements. Critics argue that arbitration clauses, presented on a "take-it-or-leave-it" basis to persons at their time of need, unfairly deprive vulnerable individuals of their right to sue. Proponents respond that arbitration does not limit liability, but merely designates an alternate forum. Detractors counter that arbitration is an inadequate substitute for a jury trial and urge that public policy requires greater scrutiny of the circumstances underlying the resident's consent. Supporters reply that public policy favors arbitration because it is fair and efficient, quicker and less expensive than litigation, and relieves court congestion. Whatever the outcome of the national debate, anecdotal evidence suggests that most nursing home patients, when offered a choice, are willing to sign arbitration agreements most of the time.

In New York, the anti-arbitration bias has a statutory basis. Under section 2801-d of the Public Health Law, a patient in a residential health care facility has the right to bring an action against the facility for injuries that he or she may suffer from the deprivation of any right or benefit guaranteed under the statute. A "right or benefit" under the statute includes "any right or benefit created or established for the well-being of the patient" under any contract or state or federal statute or regulation.¹ This includes the full panoply of patient rights under state and federal regulation, including the right to receive adequate and appropriate medical care.²

Under subsection 7 of the statute, any waiver of the right to commence an "action" under section 2801-d, "whether oral or in writing, shall be null and void and without legal force or effect." Likewise, under subsection 8, any waiver of the right to a trial by jury "whether oral or in writing, prior to the commencement of an action, shall be null and void, and without legal force or effect." The effect of these provisions is to

invalidate any pre-dispute agreement to arbitrate claims arising under section 2801-d.

The thesis of this article is that the time has come to reconsider the rule prohibiting the use of arbitration clauses in nursing home agreements in New York. The Federal Arbitration Act (FAA)³ requires the enforcement of written arbitration agreements in transactions "involving commerce." In a series of recent cases, the United States Supreme Court has extended the FAA's reach to the limits of congressional Commerce Clause power under the U.S. Constitution. This has prompted state supreme courts in other states to hold that nursing home admission agreements evidence transactions involving commerce to which the FAA applies and to enforce arbitration agreements between a nursing home and its patients. For the reasons discussed below, the rationale underlying these cases applies fully to the statutory limitations on the arbitration of claims under section 2801-d of the Public Health Law.

When Does the FAA Apply?

The FAA's central provision, section 2, states that in any contract "involving commerce" a written agreement to submit an existing or future dispute to arbitration "shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract." The statute reflects "a congressional declaration of a liberal federal policy favoring arbitration agreements, notwithstanding any state substantive or procedural policies to the contrary." It requires the enforcement of arbitration agreements in transactions involving commerce, and it pre-empts state statutes disfavoring or prohibiting arbitration for a particular class of transactions.

The test for whether a contract evidences a "transaction involving commerce" is whether "in the aggregate the economic activity in question would represent 'a general practice . . . subject to federal control.'"⁶ The term "involving commerce" is the functional equivalent of the more familiar phrase "affecting commerce." Both are terms of art reflecting the broadest permissible exercise of Congress' Commerce Clause power. The term "involving commerce" actually encompasses a wider range of transactions than the term "in commerce," that is, "within the flow of interstate commerce." It signals "Congress' intent to provide for the enforcement of

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arbitration agreements within the full reach of the Commerce Clause."⁷

Under recent Supreme Court pronouncements, the fact that a transaction appears to be "local" in nature does not necessarily mean that the FAA is inapplicable to the parties' agreement. In Citizens Bank v. Alafabro, Inc.,8 an Alabama bank sought to compel arbitration of a financial dispute with an Alabama construction company relating to a decade-long series of commercial loan transactions. The bank had signed "renewal notes" restructuring the previous loans, and the restructuring arrangements included arbitration clauses covering "all disputes, claims, or controversies." After the second restructuring, Alafabro sued the bank in Alabama state court on a variety of state law theories. The Alabama Supreme Court, viewing the transaction as inherently local in nature, refused to compel arbitration. The U.S. Supreme Court reversed.

The Supreme Court held that the test for whether a contract evidences a transaction involving commerce is whether "in the aggregate the economic activity in question would represent 'a general practice . . . subject to federal control." Under this formulation, it is not essential that the agreements at issue—in that case the debt-restructuring agreements—in and of themselves have a "substantial effect on interstate commerce." Instead, the Court held, "[o]nly that general practice need bear on interstate commerce in a substantial way."9 The restructured loan agreements satisfied this test for three reasons: first, the construction company used funds from the restructured loans in construction projects throughout the southeastern U.S.; second, the company secured the restructured debt with all of its assets, including out-of-state inventory; and third, the "general practice" of commercial lending has a broad impact on the national economy, thereby invoking congressional power to regulate it under the Commerce Clause. Thus, the Court concluded, the FAA applied.

The Court's holding in *Citizens Bank* was an extension of its conclusion in *Allied-Bruce Terminix*, ¹⁰ that a contract between an exterminating company and a homeowner for lifetime residential termite control services evidenced a "transaction involving commerce" to which the FAA applied. Even though the exterminating contract was "local" in nature, the pertinent inquiry was whether the underlying transaction that the contract "evidenced" involved interstate commerce. It did, the Court concluded, both because the exterminating company did business in several states and because the termite-treating and house-repairing materials it had used to carry out the contract had come from outside Alabama. ¹¹

As these cases make clear, the FAA applies where the overall transaction is one "involving commerce." This is so, even if the relationship between the contracting parties is otherwise local in nature and even if the parties did not contemplate any interstate commerce connection at all. As applied to nursing homes, the relevant inquiry then is whether the operation of a nursing home represents a general practice subject to federal control.

Does the FAA Apply to Nursing Home Agreements?

There is a strong basis to conclude that the business of operating a nursing home represents a general practice subject to federal control to which the FAA applies. A number of factors common to nursing homes support this conclusion.

First, nursing homes are subject to pervasive federal regulation. Among other things, federal law establishes the minimum requirements for nursing home participation in the Medicare and Medicaid programs. ¹² The federal Centers for Medicare and Medicaid Services (CMS) have promulgated regulations and standards based upon the statutory requirements. ¹³ The federal statutes establish a survey and certification process to assess compliance with the federal requirements, and nursing homes are subject to federal statutory sanctions for noncompliance.

Second, nursing homes in the aggregate exert a substantial economic impact on interstate commerce. The Medicare and Medicaid programs cover much of the cost of nursing homes, and payments to nursing homes under these programs consume a significant portion of the federal budget. Since 1998, Medicare's reimbursement system for skilled nursing facility care has been a prospective payment system, which includes an adjustment based on the Resource Utilization Groups to which Medicare residents are assigned. The federal government's involvement in nursing home rate-setting activity reflects a significant federal interest in and control over the nursing home industry.¹⁴

Third, nursing homes make extensive use of equipment, products and materials that come from outside of New York state and pass through interstate commerce. These include construction supplies, moveable inventory, medical diagnostic equipment, food, prescription drugs, and cleaning supplies, among many other items. ¹⁵ These factors, taken individually or together, render the operation of a nursing home a "general practice . . . subject to federal control."

There is judicial precedent for this conclusion. Under a growing body of case law, the FAA applies to

nursing homes, and it pre-empts state statutes disfavoring or prohibiting binding arbitration agreements between a nursing home and its residents.

In Owens v. Coosa Valley Health Care, Inc. 16 and Briarcliff Nursing Home, Inc. v. Turcotte, 17 the Alabama Supreme Court held that the activities of nursing homes substantially affected interstate commerce within the scope of the FAA. In Owens, the nursing home demonstrated that it purchased most of its equipment and supplies from out-of-state suppliers, had patients from other states, was governed by federal regulations, and received 95 percent of its income from the Medicaid and Medicare programs. Without these out-of-state supplies and equipment, and the federal funds, the nursing home could not have provided services to its patients. In Briarcliff, the nursing home established that its regional office was in Florida, its headquarters were in Maryland, several patients were from other states, it received regular shipments of supplies and purchased medicine from out-of-state suppliers, and the patient whose care was at issue was a Medicare recipient. Given these factors, the Alabama Supreme Court concluded in both cases that the underlying transaction the provision of nursing home care—involved interstate commerce under the FAA.18

In *In re Nexion Health at Humble, Inc.,* ¹⁹ the Texas Supreme Court held that just one of these factors—evidence of Medicare payments to the nursing home on the patient's behalf—was sufficient to establish interstate commerce within the scope of the FAA. The court further held that the FAA pre-empted the Texas Arbitration Act because the state statute added an additional requirement—the signature of a party's counsel—to arbitration agreements in personal injury cases and thereby interfered with the enforceability of arbitration agreements with respect to that class of transactions. ²⁰

And in *Vicksburg Partners*, L.P. v. Stephens, ²¹ the Mississippi Supreme Court concluded that individual agreements between a nursing home and its patients, when taken in the aggregate, represent a general practice subject to federal control within the scope of the FAA. The court recognized that nursing homes, through general practice, including, "basic daily activities like receiving supplies from out-of-state vendors and payments from out-of-state insurance companies or the federal Medicare program," have an effect on interstate commerce. Additionally, the court noted, the defendants in that case, which included out-of-state corporations, collectively contributed to the operation of the nursing home, which in turn received goods and services from out-of-state vendors, took in out-of-state residents, and received payments from out-of-state insurance carriers, including the Medicare and Medicaid programs.

What Are the Implications of Section 2801-d?

The implication for cases under section 2801-d of the Public Health Law is clear. The FAA not only "declared a national policy favoring arbitration," but actually "withdrew the power of the states to require a judicial forum for the resolution of claims which the contracting parties agreed to resolve by arbitration."²² The FAA pre-empts conflicting state anti-arbitration laws, and states cannot apply their anti-arbitration rules to invalidate arbitration clauses in agreements evidencing a transaction in commerce.

As noted above, subsection 7 of section 2801-d invalidates any waiver of the right to bring an "action" under that statute. Subsection 8 nullifies "any waiver of the right to a trial by a jury, whether oral or in writing, prior to the commencement" of such an action. These are not grounds that exist at law or in equity "for the revocation of any contract" but only for the revocation of arbitration clauses in nursing home agreements. The application of these anti-arbitration rules would not advance the goals of the FAA by encouraging the enforcement of arbitration clauses in nursing home admission agreements. In practice, it has the opposite result, all but eliminating the arbitration of disputes between a resident and the nursing home, except perhaps for a narrow class of disputes relating to non-payment of fees.²³ The statutory limitations on the waiver of the right to bring an "action" or to trial by jury place arbitration agreements in a class apart from other contracts and limits the validity of such agreements.

Under the FAA, there is a strong presumption in favor of arbitration. Given this presumption, and precedents from other states discussed above, New York courts, if presented with the issue, could well conclude that the FAA applies to nursing homes and that it preempts state statutory restrictions against the use of binding arbitration agreements between the nursing home and its residents. This would include restrictions on waiving the right to commence an action in court or a trial by jury in an action under section 2801-d.

What is CMS' Position on the Use of Binding Arbitration in Nursing Home Agreements?

CMS has adopted a hands-off approach to the use of binding arbitration to resolve disputes between a resident and the nursing home. Specifically, according to a memorandum dated January 9, 2003,²⁴ CMS views the issue of arbitration as a matter between the resident and the nursing home. The federal regulations, as presently

construed, thus would not bar the use of arbitration clauses in nursing home admission agreements.

At the same time, however, CMS cautions that there may be consequences if the nursing home tries to enforce the arbitration agreement in a way that violates federal law, including the rules governing resident discharge and transfer, the obligation to furnish an abusefree environment, and other requirements bearing on the facility's obligation to provide quality care to all residents.²⁵ For example, a nursing home cannot require a current resident to sign a new admission agreement with a binding arbitration clause. It cannot discharge or retaliate against a resident for failing to sign or to comply with a binding arbitration agreement. If it does, according to CMS, the state or regional offices may commence an enforcement action under the rules governing program participation for long-term care facilities.

What Other Grounds May Exist for the Revocation of Arbitration Agreements?

The FAA requires states to enforce arbitration agreements, except to the extent that there are grounds to revoke the agreement under state law generally. The final clause of section 2, "save upon such grounds as exist at law or in equity for the revocation of any contract," has been interpreted to save "generally applicable contract defenses, such as fraud, duress, or unconscionability" from federal pre-emption.²⁶

Mutual assent to the essential term of a contract is required in order for there to be an enforceable contract. In the absence of fraud or other wrongful acts, a party who signs or accepts a written contract is conclusively presumed to know its contents and to assent to them. As a general rule, courts will not inquire into whether there was subjective agreement as to each clause in the contract. Rather the focus is on whether there was an objective agreement with respect to the entire contract.

An unconscionable agreement is unenforceable under New York law.²⁷ An unconscionable contract is one that is "so grossly unreasonable or unconscionable in the light of the mores and business practices of the time and place as to be unenforceable according to its literal terms."²⁸ Under New York law, a determination of unconscionability generally requires a showing that the contract was both procedurally and substantively unconscionable when made—i.e., "some showing of an 'absence of meaningful choice on the part of one of the parties together with contract terms which are unreasonably favorable to the other party.'"²⁹ Courts focus on evidence of high pressure or deceptive tactics, the use of fine print in the contract, the experience and educa-

tion of the party claiming unconscionability, and whether there was disparity in bargaining power. Inequality in bargaining power alone, however, is generally not sufficient to render an arbitration agreement unenforceable. A contract is substantively unconscionable where its terms unreasonably favor the stronger party. Generally, arbitration agreements that are binding on both parties are not considered to unreasonably favor the stronger party.³⁰

Two cases in the health care arena, both from Tennessee, provide a helpful road map for the application of these common law principles to nursing homes. In Buraczynski v. Eyring, 919 S.W.2d 314 (1996), the Tennessee Supreme Court upheld an arbitration agreement between patients and health care providers because it did not contain oppressive or unconscionable features. The arbitration clauses were not hidden within a larger agreement, but were in separate, one-page agreements with the heading, "Physician-Patient Arbitration Agreement." The agreement clearly informed the patient that, "by signing this contract you are giving up your right to a jury or court trial" for any medical malpractice claim. There were no buried provisions. The agreement clearly laid out all of the terms, including a provision binding the patient's spouse and heirs. There was a short explanation attached to each document encouraging the patient to ask questions about the agreement. The arbitration procedures were balanced, with each side choosing one arbitrator and the two arbitrators then appointing the third arbitrator. Both sides would be bound by the arbitrators' decision. The patient had the right to revoke the agreement within 30 days. Significantly, the agreements did not change the doctor's duty to use reasonable care in treating patients, or limit his liability for breach of that duty, but merely shifted the disputes to a different forum.

In *Howell v. NHC Healthcare-Fort Sanders*,³¹ in contrast, the court refused to enforce an arbitration agreement between a nursing home and a resident. According to the plaintiff, who could not read, an employee "pushed" the documents in front of him and asked him to sign without explanation. The plaintiff's daughter testified that she did not recall the nursing home employee even using the word "arbitration." The nursing home employee testified that she explained the agreement, but never explained that the plaintiff was giving up his right to a jury trial. Under the circumstances, the court held, the nursing home failed to show that the parties bargained over the arbitration provision or that it was within the reasonable expectation of the ordinary person under the circumstances.

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Nursing homes considering the inclusion of arbitration clauses in their admission agreements should be prepared to establish mutual assent to the terms of the contract. Among other things, the arbitration provisions should be drafted in plain language to give clear notice of the pertinent terms, especially the waiver of the right to a jury trial. The pertinent terms should be prominent and conspicuous, not "hidden" within other types of contracts. The arbitration procedures should be balanced, fair, and binding on both sides. The nursing home should give the resident and his or her representative a reasonable opportunity to study the contract and to inquire about the meaning and significance of the contract terms. It should consider allowing the resident a reasonable period, such as 30 days, to revoke the agreement to arbitrate with no adverse consequences on the terms of the residency. The focus should be on ensuring that the resident and/or his or her representative mutually agreed, in a knowing, intelligent and voluntary manner, to forgo the right to a trial by jury in an action in court.

Recommendations and Conclusion

Under a growing trend of authority, nursing homes evidence transactions involving commerce to which the FAA applies, and the FAA pre-empts state anti-arbitration statutes that apply to nursing home agreements. There are strong grounds to argue that New York courts, if presented with the issue, should conclude that the FAA applies to nursing homes and that it pre-empts statutory restrictions against the use of binding arbitration agreements between a nursing home and its residents in an action under section 2801-d.

The FAA does not pre-empt other principles of state law relating to contract formation generally, such as fraud, duress, and unconscionability. Therefore, the nursing home seeking to include an arbitration clause in its residency agreements should be prepared to establish that the resident has knowingly, intelligently and voluntarily waived the right to a trial by jury and thereafter to ensure that it does not enforce the agreement in a way that would violate federal program participation requirements.

Endnotes

- N.Y. Pub. Health Law § 2801-d. This would include the full panoply of patient rights and responsibilities under state and federal regulation, including the right to receive adequate and appropriate medical care. It is a defense to liability that the facility "exercised all care necessary to prevent and limit the deprivation." Id. at § 2801-d(1).
- 2. See, e.g., N.Y. Pub. Health Law § 2803-c; 10 N.Y.C.R.R. §§ 415.1, et sea.
- 3. 9 U.S.C. § 2.

- 4. Id
- See, e.g., Moses H. Cone Mem. Hosp. v. Mercury Constr. Corp., 460 U.S. 1, 24 (1983).
- Citizens Bank v. Alafabro, 539 U.S. 52, 56 (2003) (per curiam);
 Allied-Bruce Terminix Co. v. Dobson, 513 U.S. 265, 273–74 (1995).
- 7. Id. Perry v. Thomas, 482 U.S. 483, 490 (1987).
- 8. 539 U.S. 52, 56–57 (2003) (per curiam).
- 9. *Id.* at 57.
- 10. 513 U.S. 265 (1995).
- 11. Id. at 281-82.
- 12. See 42 U.S.C. §§ 1395i-3, 1396r.
- 13. See 42 C.F.R. Part 483, Subpart B (Requirements for Long-Term Care Facilities).
- See generally Citizens Bank, 539 U.S. at 58 ("general practice" of commercial lending, which has broad impact on national economy, sufficient to invoke FAA).
- See generally Allied-Bruce Terminix, 513 U.S. at 282 (party's use of out-of-state products to carry out contract supported conclusion that contract "evidenced" a "transaction" involving interstate commerce within scope of FAA).
- 16. 890 So.2d 983 (Ala. 2004).
- 17. 894 So.2d 661 (Ala. 2004).
- See also Community Care of America of Alabama, Inc. v. Davis, 850
 So.2d 283 (Ala. 2002) (holding that nursing home had a nexus
 with interstate commerce, but prohibiting enforcement of arbitration clause under state law because facility did not possess a
 valid certificate of authority).
- 48 Tex. Sup. J. 805, 2005 Tex. LEXIS 422, No. 04-0360, 2005 WL (Tex. May 27, 2005).
- See also In re Ledet, 2004 Tex. App. LEXIS 11474 (Tx. Ct. App, 4th Dist. 2004) (holding that FAA applied to nursing home arbitration agreement expressly providing that FAA applied, without need to consider nexus with interstate commerce).
- 21. 2005 Miss. LEXIS 607 (Miss. Sept. 22, 2005).
- 22. Southland v. Keating, 465 U.S. 1, 10 (1984).
- See, e.g., Rego Park Nursing Home v. Kraughto, 302 A.D.2d 269
 (App. Div. 1st Dep't 2003) (arbitration clause empowering arbitrator to resolve claims by nursing home against resident for non-payment of charges).
- The memorandum is available at http://www.cms.hhs.gov/ medicaid/survey-cert/sc0310.pdf.
- 25. See 42 C.F.R. § 483.13(b).
- 26. See Doctor's Assocs. v. Casarotto, 517 U.S. 681, 687 (1996).
- 27. Gillman v. Chase Manhattan Bank, 73 N.Y.2d 1 (1988).
- 28. Id. at 10.
- 29. Id. (citations omitted).
- See Baldeo v. Darden Restaurants, Inc., 2005 U.S. Dist. LEXIS 289 (S.D.N.Y. Jan. 11, 2005) (applying New York law).
- 31. 109 S.W.3d 731, 734 (Tenn. Ct. App. 2003).

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The Assisted Living Reform Act of 2004: New Models of Care, New Choices for Consumers

By Alan J. Lawitz

On October 26, 2004, Governor George Pataki signed into law the Assisted Living Reform Act of 2004 (ALRA).¹ This article will explain how the ALRA came about, describe its provisions, discuss the present state of its implementation and identify several issues relating to such implementation that should be of interest to attorneys representing consumers and providers, as well as government regulators.

I. Background

A. Adult Care Facilities

In order to understand the new Assisted Living Residences (ALRs) created under the ALRA, it is necessary to have a basic working knowledge of adult homes and enriched housing programs. Adult homes and enriched housing programs are types of "adult care facilities" (ACFs) licensed and inspected by the New York State Department of Health (DOH).² They provide room and board, supervision, case management, activities and some personal care. Personal care is defined as assistance with activities of daily living such as bathing, dressing, grooming, toileting and with medications.³ The services provided in enriched housing programs are similar to those provided in adult homes, although enriched housing programs are in apartments, while adult homes are in a more congregate setting. While ACFs are designed for persons who are unable or substantially unable to live independently, they have some significant limitations. ACFs are not intended for persons who are in need of continual nursing or medical care. Unlike a nursing home, they are not staffed with nurses, doctors, or rehabilitation specialists for therapies, nor do they have a medical director.

Regulations state that an operator of an ACF shall not accept or retain a resident who: is in need of continual nursing or medical care; has a medical condition which is unstable and which requires continual skilled observation of symptoms and reactions or skilled recording of such skilled observations; is chronically bedfast, chairfast, unable to transfer or chronically requires the assistance of another to transfer, walk, climb or descend stairs (unless on a ground floor); has chronic unmanaged incontinence; or is dependent on certain types of medical equipment.⁴ In other words, an ACF is not designed to allow a resident to "age in place" as their need for nursing, medical or increased

personal care and supervision extends beyond what the ACF statute and regulations permit.

B. Rise of the "Look-alikes"

In the 1990s there began a national trend of a combination of housing and services which was generically called "assisted living." Models of assisted living varied widely throughout the country in terms of the scope of services provided, eligibility standards and regulatory framework.

A number of such "assisted living" models developed in New York that encouraged or permitted aging in place. Most of these operations were not licensed, perhaps in part because there was no regulatory model that permitted residents to age in place outside of a nursing home setting. They were set up to provide a less institutional, more home-like, long-term-care alternative to nursing homes. They looked like ACFs but were not licensed as such; as a result, some referred to such places as "look-alikes." Some of those places called themselves assistive living to try to make the point that they were not *licensed* assisted living or an ACF; some providers felt their model did not really fit the ACF category. In some cases, the DOH pursued enforcement action against what the agency regarded as "scofflaw" facilities that needed to be licensed as ACFs.

On the one hand, providers felt there was a need for a more home-like setting that promoted aging in place, to meet market demands. On the other hand, consumers and regulators were concerned that such activity needed to be subject to state licensure, and there needed to be clear enforceable standards in place to provide resident protection.

C. Confusion Regarding Term "Assisted Living"

In addition, there was great confusion about what the term "assisted living" meant in New York. Many were using the term, but it had no specific legal meaning in this state. There was an existing statutory program called the Assisted Living Program (ALP). The ALP combined an adult home, or enriched housing program with a type of licensed or certified home care, and was paid for by a Medicaid rate as well as SSI.⁵ But in general the term "assisted living" was used for much more than the relatively small ALP. "Assisted living" was used in marketing and otherwise to describe places

which were unlicensed as well as those that were licensed. Some residents and their families mistakenly believed that their particular residence was licensed simply because it was described as "assisted living." Furthermore, many consumers found to their chagrin that the unlicensed setting in which they were residing was not covered by their long-term care insurance policy because they were not in a recognized, state-licensed category of care, as many policies required.

Interest grew in the need for changes to the law. In 1999 a report to the Governor and Legislature was issued, declaring there was a need for a clear and consistent definition of assisted living; that assisted living needs to assure adequate protection of the health and safety needs of residents through state oversight; and that such legislation must provide resident dignity and choice, and protect resident rights.⁶ A Governor's Program Bill was introduced in 1999 on assisted living, and bills were also introduced by the Senate and Assembly.⁷ The Senate held legislative hearings to solicit views on assisted living. Operators of home care, nursing homes, ACFs, providers of services for persons with dementia and mental illness, as well as consumers, weighed in on the debate. Over the next several years there was a variety of legislative proposals and continuing discussion. Finally, several regulators, legislators, consumers and providers joined together to develop and support the bill signed into law.

II. What Does the Act Do?

A. Legislative Purpose

In passing the ALRA, the Legislature sought to clarify in statute what "assisted living" means in New York state and to ensure that any entity that provides or calls itself "assisted living" or any similar term is properly licensed and subject to state inspection and supervision.

The Legislature declared that "congregate residential housing with supportive services in a home-like setting, commonly known as assisted living, is an integral part of the continuum of long-term care. Further, the philosophy of assisted living emphasizes aging in place, personal dignity, autonomy, independence, privacy and freedom of choice." The legislation also requires a written residency agreement that contains consumer protections, enunciates and protects resident rights, and provides adequate and accurate information for consumers.⁸

B. Uniform Definition of Assisted Living

First and foremost, the ALRA provides a uniform definition of and statutory framework for assisted living in New York state. "Assisted living" is defined as:

an entity which provides or arranges for housing, on-site monitoring, and personal care and/or home care services (either directly or indirectly), in a home-like setting to five or more adult residents unrelated to the assisted living provider. An applicant for licensure as assisted living that has been approved in accordance with the provisions of this article must also provide daily food service, twenty-four hour on-site monitoring, case management services, and the development of an individualized services plan for each resident.

The definition further provides that the operator "shall provide each resident with considerate and respectful care and promote the resident's dignity, autonomy, independence and privacy in the least restrictive and most home-like setting commensurate with the resident's preference and physical and mental status."

The ALRA requires the DOH to define in regulations "independent senior housing" for purposes of determining certification both as an ACF under Social Services Law (SSL) article 7, and as an ALR under article 46-b of the Public Health Law (PHL).9

Implementation Note

DOH has issued guidance stating that for the purpose of determining the necessity to become licensed as an ALR the term Independent Senior Housing shall mean:

- § 1 A housing setting serving seniors in which no individual or entity provides, arranges for or coordinates (either directly or indirectly), on-site monitoring as defined by PHL § 4651 (12), and either personal care or home care services for five or more residents of such housing setting unrelated to the housing provider; and in which
- § 2 Neither the housing setting nor other services provided in such setting are advertised or marketed to the public as assisted living, assistive living or any derivation of such terms.

The provision, arrangement or coordination of one or more of the following services shall not, in itself, require licensure as an ALR: room, board, laundry, housekeeping, transportation, information and referral, case management, security or "concierge"-like services. ¹⁰

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C. Licensure Required

In order to operate an ALR, an operator must also be licensed by the DOH as either an adult home or an enriched housing program. An applicant for ALR licensure may apply for both the ALR and either the adult home or enriched housing program licenses simultaneously. The statute states:

No entity shall establish, operate, provide, conduct, or offer assisted living in [New York], or hold itself out as an entity which meets the definition of assisted living or advertise itself as assisted living or by a similar term, without obtaining the approval of the [DOH] to operate as an adult care facility pursuant to title two of article seven of the Social Services Law, obtaining the approval of the [DOH] as required in this article, and otherwise acting in accordance with this article.¹¹

The knowing operation of an assisted living residence without the prior written approval of the [DOH] shall be a class A misdemeanor.

The ALR application, in a format to be developed by the DOH, must contain: the business name, street address and mailing address of the residence and of the owners of the residence; the status of any current operating certificates held by the applicant; a copy of the residency agreement and disclosures to be given to prospective residents in accordance with this article; and any other information the DOH may deem necessary, provided such information does not duplicate what is otherwise required of an applicant in obtaining an adult home or enriched housing program license.¹²

An ALR operator shall comply with all applicable statutes, rules and regulations required for maintaining a valid operating certificate issued to an adult home or enriched housing program under title two of article seven of the SSL.¹³ However, where a provision in PHL article 46-b is in conflict with a provision in SSL article 7, or regulations promulgated pursuant to such article, the SSL article 7 provision or regulation is superseded.¹⁴ Approval of licensure or certification pursuant to PHL article 46-b may be granted only to an applicant who satisfactorily demonstrates:

- (1) that the applicant possesses (or applies for and obtains) a valid operating certificate to operate an adult home or enriched housing program (for the purposes of this article the term ACF will be used to refer to an adult home or enriched housing program);
- (2) that any such applicant which has an existing ACF operating certificate is in good standing, meaning the applicant has not: received any official notice from the DOH of a proposed action against its operating cer-

tificate; within the previous three years been assessed a civil penalty after a hearing for a violation that has not been rectified; within the previous year, received official written notice of the proposed assessment of a civil penalty for a violation alleged to have resulted in harm or endangerment to a resident; or been subject to one of several other enforcement actions described in the statute.¹⁵

The DOH is authorized to approve an applicant that would not be in "good standing" as provided in PHL § 4656(3)(b) if it determines that the applicant otherwise meets the requirements of this section and that the applicant is of good moral character and is competent to operate the residence.

Any applicant that does not have an existing valid ACF operating certificate is required to have a full character and competence review performed by the DOH as part of the application process. As part of its review of applicants who are currently licensed ACF operators but who do not meet the "good standing" criteria, or applicants who do not have an existing valid operating certificate, the DOH shall, on its web page, solicit and consider public comment;

- (3) that the applicant has adequate financial resources to provide such assisted living as proposed;
- (4) that the building, equipment, staff, standards of care and records to be employed in the operation comply with applicable local law; and
- (5) that any license or permit required by law for the operation of such residence has been issued to such operator.

Every assisted living residence shall be licensed on a biennial basis and shall pay a biennial license fee and additional fees if it operates at higher levels of care for which additional certification is required.¹⁶

Implementation Note

On June 3, 2005, DOH issued a Dear Operator Letter which provides an overview of the ALRA and to which was attached the application for licensure as an ALR. The letter includes reference to several additional guidance documents available through the DOH website to assist applicants.¹⁷

D. Admission to Assisted Living

An operator must conduct an initial pre-admission evaluation of a prospective resident to determine whether or not the individual is appropriate for admission. Such evaluation shall be conducted by the operator and, if necessary, in conjunction with a home care

services agency or appropriate employee. An evaluation tool approved by the DOH must be used in such evaluations. The operator shall not admit any resident if the operator is not able to meet the care needs of the resident within the scope of services authorized under the ALRA and the individualized service plan; provided further that no operator shall admit any resident in need of 24-hour skilled nursing care.¹⁸

Implementation Note

A draft evaluation tool has been prepared by a multi-agency work group led by DOH. This document is being reviewed as of this writing by the Taskforce on ACFs and ALRs (the Taskforce), described later in this article.

E. Individualized Services Plan

A written individualized service plan (ISP) must be developed for each resident upon admission. The ISP shall be developed with the resident, resident's representative and resident's legal representative, if any; the operator; and, if necessary, a home care services agency. The initial ISP will be developed in consultation with the resident's physician. If the physician determines that the resident is not in need of home care services, a home care services agency need not participate in the development of the ISP.

The ISP will take into account the medical, nutritional, rehabilitation, functional, cognitive and other needs of the resident. The ISP will include the services to be provided, and how and by whom services will be provided and accessed. The ISP will be reviewed and revised as frequently as necessary to reflect the changing care needs of the resident, but no less frequently than every six months. To the extent necessary, such review and revision will be undertaken in consultation with the resident's physician.¹⁹

Implementation Note

DOH is in the process of preparing additional guidance relative to ISP requirements. This document will be presented to the Taskforce for review and comment.

F. Aging in Place; Enhanced Assisted Living Certificate

The term "aging in place" is defined in the ALRA as care and services at a residence that possesses an Enhanced Assisted Living Certificate which, to the extent practicable, within the scope of services set forth in the residency agreement, accommodates a resident's changing needs and preferences to allow such resident to remain in residency as long as the residence is able and authorized to accommodate the resident's needs.²⁰

The statute authorizes, but does not require, applicants for an ALR to seek an additional certification called an Enhanced Assisted Living Certificate. An Enhanced Assisted Living Certificate will authorize the assisted living residence to provide aging in place by retaining residents who: (a) are chronically chairfast and unable to transfer, or chronically require the physical assistance of another person to transfer; (b) chronically require the physical assistance of another person in order to walk; (c) chronically require the physical assistance of another person to climb or descend stairs; (d) are dependent on medical equipment and require more than intermittent or occasional assistance from medical personnel; or (e) have chronic unmanaged urinary or bowel incontinence.²¹ An Enhanced Assisted Living Certificate is required for any ALR that wants to allow residents to "age in place."

An applicant for an Enhanced Assisted Living Certificate must submit a plan showing how the additional needs of residents will be safely and appropriately met at such residence. The plan must include, at a minimum, a written description of services, staffing levels, staff education and training, work experience and any environmental modifications that have been made or will be made to protect the health, safety and welfare of such persons.

An operator of an Enhanced Assisted Living Residence (EALR), meaning an operator with an Enhanced Assisted Living Certificate, may hire care staff directly pursuant to standards developed by the DOH, or may contract with a home care services agency approved to operate under PHL article 36.

Comment

It is important to note that, while the operator of an adult home, enriched housing program and even the basic level of ALR is not authorized under such license to directly hire nurses to provide nursing services to their residents, the operator of an EALR may opt to do so, or may choose to have nursing services provided by a home care provider approved under PHL article 36.

Implementation Notes

DOH has issued additional guidance in an EALR Overview document available on its website. The skilled nursing and medical needs of its residents may be met either directly by the operator or externally through a home care services agency. DOH will require an EALR to have at least one licensed practical nurse present in the residence 24 hours a day, 7 days a week. Registered nurses must be either on-site in the residence or on-call 24 hours a day, 7 days a week. This

SPECIAL EDITION: SELECTED TOPICS IN LONG-TERM CARE LAW

overview document also addresses such issues as admissions/retention standards, service provision, staffing and structural requirements.²²

Certain operators of adult homes and enriched housing programs have received waivers under the Retention Standards Waiver Program, a program which has allowed these ACFs to retain certain residents whose needs exceed ACF regulatory criteria. The DOH has advised that it is phasing out this program because the EALR takes its place. Those operators who have such waivers may keep these in place, but only for the particular residents who are currently retained under the Retention Standard Waiver Program. Once these residents are no longer in residence, the waivers will terminate.

No resident may be permitted to continue to age in place under the terms of an Enhanced ALR Certificate unless the operator, the resident's physician and, if applicable, the resident's licensed or certified home care agency, agree that the additional needs of the resident can be safely and appropriately met at the residence. It should be noted that even in the EALR level of care, no resident may be *admitted* who needs 24-hour skilled nursing care.

If a resident reaches the point where he or she is in need of 24-hour skilled nursing care or medical care required to be provided by facilities licensed pursuant to article 28 of the PHL or articles 19, 31 or 32 of the Mental Hygiene Law, then the general rule would be that the resident must be discharged from the residence and the operator must initiate proceedings for the termination of the residency agreement in accordance with the provisions of SSL § 461-h. However, a resident may remain at the residence if each of the following conditions are met:

- (a) the resident hires appropriate nursing, medical or hospice staff to care for the resident's increased needs;
- (b) the resident's physician and home care services agency both determine and document that, with the provision of such additional nursing, medical or hospice care, the resident can be safely cared for in the residence and would not require placement in a hospital, nursing home or other higher level of care facility;
- (c) the operator agrees to retain the resident and to coordinate the care provided by the operator and the additional nursing, medical or hospice staff; and

(d) the resident is otherwise eligible to reside at the residence.²³

Comment

The ability of an operator of an EALR to retain a person who requires 24-hour skilled nursing or medical care is a major provision of the ALRA. This is a new model of care that will permit persons who previously would have required nursing home care to be retained in the more home-like setting of an ALR. This is consistent with the Supreme Court's Olmstead decision in terms of affording a less restrictive alternative to institutionalization to persons with disabilities.²⁴ It must be noted, however, that it will be up to the ALR operator, in consultation with, and upon documentation by the resident's physician and if necessary, the home care provider, to determine whether the resident can be safely cared for in the EALR setting. The task of assuring quality of care for persons with 24-hour skilled care needs in a less institutional setting will pose both new opportunities and new challenges for providers and regulators.

G. Special Needs Certificate

Any residence that advertises or markets itself as serving persons with special needs, including, but not limited to, dementia or cognitive impairments, must submit an application to DOH for a Special Needs Certificate. The application must include a special needs plan setting forth how the special needs of such residents will be safely and appropriately met, including, but not limited to, a written description of specialized services, staffing levels, staff education and training, work experience, professional affiliations or special characteristics relevant to serving persons with special needs, and any environmental modifications that have been or will be made to protect such persons in the residence. The DOH shall develop standards for approval of an application for a Special Needs Certificate to ensure adequate staffing and training to meet the needs of the residents. The standards will be based on the recommendations of the Taskforce on ACFs and ALRs created under this ALRA.25

Comment

The statute states that in order to be required to be licensed as an ALR with a Special Needs Certificate, the residence must *advertise or market itself* as serving persons with special needs. If the residence does not so advertise itself, there may not be a requirement for a Special Needs Certificate. If, however, the residence provides housing, personal care or supervision to five or more persons unrelated to the operator, the residence may be subject to licensure as an ACF, whether or not it

advertises itself as caring for persons with special needs.

It is also important to distinguish between an ALR that is specifically set up to serve persons with a particular special need (such as dementia) and that advertises itself as such, and a basic ALR or ACF that offers such services to a general population, which may include some persons with the particular special need. The former requires a Special Needs certification; the latter does not.

Implementation Note

In its June 3, 2005, Letter to Operators, DOH advised that all licensed ACFs that operate currently approved dementia facilities or units will be required to apply for ALR and a Special Needs Certificate. Such operators will need to review the revised requirements for such certification issued by DOH and provide the DOH with a description of any changes that will be made in their programs as a result. DOH has also issued a "Special Needs Assisted Living Plan Overview and Requirements" document, which is available on its website to provide additional guidance to prospective operators.²⁶

III. Consumer Protections

A. Residency Agreement and Disclosures (PHL § 4658)

1. Residency Agreement

The operator must execute with each resident a written residency agreement, in no less than 12-point type and written in plain language, which complies with numerous detailed requirements of the ALRA.²⁷ Such agreement shall be dated and signed by the operator, the resident and the resident's representative and legal representative, if any, and any other party to be charged under the agreement. The resident, resident's representative and legal representative, if any, shall be given a complete copy of the agreement and all supporting documents or attachments and any changes whenever changes are made to the documents.

The residency agreement must include, at a minimum:

- (a) the name, telephone number, street address and mailing address of the residence;
- (b) the name and mailing address of the owner of the residence and at least one natural person authorized to accept personal service on behalf of such owner;

- (c) the name and address of the assisted living operator and at least one natural person authorized to accept personal service on behalf of the operator;
- (d) a statement, to be updated as necessary, describing the licensure or certification status of the assisted living operator and any provider offering home care services or personal care services under an arrangement with the residence, including a specific listing of such providers;
 - (e) the effective period of the agreement;
- (f) a description of the services to be provided to the resident and the base rate to be paid by the resident for those services;
- (g) a description of any additional services available for an additional, supplemental, or community fee from the operator directly or through arrangements with the operator, stating who would provide such services, if other than such operator;
- (h) a rate or fee schedule, including any additional, supplemental or community fees charged for services provided to the resident, with a detailed explanation of which services and amenities are covered by such rates, fees or charges;
- (i) a description of the process through which the agreement may be modified, amended or terminated, and setting forth the terms and time frames under which the agreement may be terminated by either party;
- (j) a description of the complaint resolution process available to residents;
- (k) the name of the resident's representative and resident's legal representative, if any, and a description of the representatives' responsibilities;
- (l) the criteria used by the operator to determine who may be admitted and who may continue to reside in the residence, including criteria related to the resident's care needs and compliance with reasonable rules of the residence;
- (m) procedures and standards for termination of contract, discharge and transfer to another dwelling or facility;
- (n) billing and payment procedures and requirements;
- (o) procedures in the event the resident, resident's representative or resident's legal representative are no longer able to pay for services provided in the residen-

SPECIAL EDITION: SELECTED TOPICS IN LONG-TERM CARE LAW

cy agreement or for additional services or care needed by the resident; and

(p) terms governing the refund of any previously paid fees or charges in the event of a resident's discharge from the ALR or termination of the residency agreement.

2. Disclosures

The operator must disclose the following information to prospective residents and their representatives as well as current residents and their representatives:

- (a) the consumer guide prepared by the DOH;
- (b) a statement listing the residence's licensure status and whether it has an Enhanced Assisted Living Certificate and/or Special Needs Certificate and the availability of any such beds;
- (c) any ownership interest in excess of 10 percent on the part of the operator in any entity which provides care, materials, equipment or other services to residents;
- (d) any ownership interest in excess of 10 percent on the part of any entity which provides care, material, equipment or other services to residents, in the operator;
- (e) a statement regarding the ability of residents to receive services from service providers with whom the operator does not have an arrangement;
- (f) a statement that the resident shall have the right to choose their health care providers, notwithstanding any agreements to the contrary;
- (g) a statement regarding the availability of public funds for payment for residential, supportive or home health services;
- (h) the DOH toll-free number for reporting of complaints regarding home care services and the services provided by the ALR operator; and
- (i) a statement regarding availability of long-term care ombudsman services and the telephone number of the local and state ombudsman.

The required disclosures must be in plain language and in 12-point type.

Implementation Note

The DOH has issued a Model Residency Agreement which includes, among other exhibits, a Disclosure Statement, an Enhanced ALR Addendum to the Residency Agreement and a Special Needs ALR Addendum

to the Residency Agreement. Those documents are available on the DOH website.²⁸

The DOH is strongly encouraging use of the Model Residency Agreement, as it will result in a more expeditious review of an ALR application. However, it will review proposed alternate language, which will be approved if it is in accordance with the requirements of the statute and applicable regulation.

B. Resident Rights

The ALRA specifies a number of resident rights intended to protect personal dignity, autonomy, independence, privacy and freedom of choice. A partial listing of these rights includes:

- providing prospective residents with sufficient information regarding the residence to make an informed choice;
- protection of civil and religious liberties, including the right to individual personal decisions and knowledge of available choices;
- 3. the right to private communication with their physician, attorney and any other person;
- the right to present grievances to the residence's staff, administrator or operator, to governmental officials, to long-term care ombudsmen, or any other person without fear of reprisal, and the right to join together with other residents or individuals to work for improvements in resident care;
- 5. the right to manage their own financial affairs;
- 6. the right to privacy in treatment and caring for their personal needs; and
- 7. the right to confidentiality in treatment of records.²⁹

Implementation Note

The Resident Bill of Rights is available on the DOH website, both as a stand-alone document and as an exhibit of the Model Residency Agreement.³⁰

C. Resident Funds

The ALRA provides that any ALR operator or employee who assumes management responsibility over the funds of a resident shall maintain such funds in a fiduciary capacity to the resident. Any interest or money received and held for the resident shall be the property of the resident.³¹

D. Rights of Residents Under SSL Article 7

Since the operator of an ALR must also be an operator of either an adult home or enriched housing program, ALR residents will also have the rights granted to residents under SSL article 7. These include, among other things, the right of an implied warranty of habitability under the residency agreement, and a resident's private right of action to enforce terms of such agreement.32 These also include significant transfer and discharge protections. An ACF operator may terminate a residency agreement and discharge a resident on an involuntary basis only on certain specified grounds and only after a 30-day notice of intention to take such action. Where the resident objects to the proposed action, the operator must commence and prevail in a special proceeding in landlord/tenant court. As a separate matter, the operator is authorized in specified situations to temporarily transfer a resident (e.g., to a hospital) if warranted by the resident's physical or mental condition. However such temporary transfer does not eliminate the operator's obligation to comply with the requirements for termination and discharge if the operator determines to take such action after the transfer.33

IV. Commissioner's Powers

The Commissioner of DOH is authorized under the ALRA to:

- develop, in consultation with the Director of the State Office for the Aging (SOFA), consumers, operators of assisted living residences, and home care providers, a consumer information guide;
- 2. promulgate, in consultation with the Director of SOFA, necessary rules and regulations to implement provisions of this article;
- receive and investigate complaints regarding the condition, operation and quality of care of any entities holding themselves out as assisted living;
- 4. make necessary investigations to procure information required to implement this article; and
- exercise all other powers and functions as are necessary to implement the provisions of this article.

It is stated that nothing in the section setting forth the Commissioner's powers under PHL article 46-b shall restrict the availability of powers otherwise available to the Commissioner under the provisions of the PHL and SSL. Any person who violates any provision of article 46-B or any rule or regulation promulgated by the DOH, or the terms of any court order or permit issued

by DOH, shall be subject to the maximum penalties which may be levied against a licensed ACF.³⁴

Implementation Notes

As of this writing, a draft of the proposed Consumer Information Guide is being reviewed both by the ALR Taskforce and by an additional group of consumers and providers. Once this product is finalized, it is anticipated that it will be available on the DOH website.

The statute expressly prohibits DOH from issuing emergency regulations to implement PHL article 46-b. DOH is in the process of developing proposed regulations.

V. Assisted Living Residence Quality Oversight Fund

Under the ALRA, a special fund is created in the joint custody of the Comptroller and the Commissioner of DOH. Such fund shall consist of all money collected by DOH pursuant to PHL article 46-B (including licensure fees, certification fees and civil penalties collected.) Any interest earned on investment of monies by such fund becomes part of the fund. The fund shall be available to DOH for the purpose of implementation of PHL article 46-b. In addition, the sum of \$500,000 will be available to the SOFA Long-Term Care Ombudsman program for the purpose of carrying out the provisions of such article.³⁵

VI. Taskforce on ACFs and ALRs

A taskforce is created under the ALRA "to update and revise the requirements and regulations applicable to [ACFs and ALRs] to better promote resident choice, autonomy and independence." The Taskforce consists of ten appointed members (six appointed by the Governor, two by the Senate, and two by the Assembly), as well as four ex-officio members (the Commissioner of DOH, Director of SOFA, Commissioner of Office of Mental Health and the Chair of the Commission for Quality of Care and Advocacy for Persons with Disabilities).

The Taskforce is also making recommendations with respect to "minimizing duplicative or unnecessary regulatory oversight;" "ensuring that the indigent have adequate access to, and that there are a sufficient number of enhanced assisted living residences;" "developing affordable assisted living;" "promoting resident choice and independence" as well as with respect to the evaluation tool and standards relating to Special Needs ALR. The Taskforce is to issue annual reports of its find-

ings and recommendations to the Governor and Legislature.

Implementation Note

The Taskforce had its first meeting on April 15, 2005, and, as of this writing, has since met on May 11, June 3, June 29, September 8, October 27, 2005 and November 22, 2005. In addition to the ex-officio members of state agencies, members include representatives of consumer organizations, proprietary and non-profit operators of adult homes and enriched housing programs, the operator of a "look-alike," and providers of care for persons with dementia. The Taskforce has been involved in the review and comment on nearly every aspect of the implementation of the program.³⁶

VII. Effective Date: Timeframes for Implementation

The ALRA became effective 120 days after being signed into law. Since the Governor signed the bill on October 26, 2004, the ALRA was effective as of February 23, 2005.

The statute states that any entity which qualifies as an ALR pursuant to PHL article 46-B and operating as an ALR on or before the effective date shall within 60 days of such effective date (that is by April 25, 2005) apply to be licensed or certified with the Commissioner of DOH in accordance with the provisions of such article and shall be required to comply with the provisions of such article upon approval of all licenses and certification for which the entity has applied.³⁷

Implementation Note

Given the very short timeframe for implementation provided under the statute, the ALR application was not available to applicants until June 3, 2005. Therefore, DOH extended the deadline for submission of the application to August 3, 2005, 61 days from its issuance.³⁸

VIII. Closing Comments

The Assisted Living Reform Act of 2004 provides several important opportunities for consumers and providers: greater clarity as to the definition of assisted living; greater assurance that the combinations of housing and services referred to as assisted living will be subject to state oversight; significant protection of consumer/resident rights; the opportunity to age in place with dignity and choice in a more home-like setting; as well as the opportunity for persons with special needs to obtain specialized care by persons with appropriate qualifications and experience.

Both representatives of providers and of consumers have spoken hopefully of the opportunity that the ALRA provides to help "raise the bar" on quality care for residents of assisted living. What this will mean in terms of final standards for care remains to be seen as implementation continues.

The flip side of opportunity is challenge. One of the challenges ahead is to ensure that a high quality of care is provided to those residents who will be "aging in place" as authorized under the ALRA, and especially those persons needing 24-hour skilled nursing or medical care. It will be extremely interesting to see how the operator of a home-like assisted living residence under the Enhanced ALR Model will coordinate both the supportive and residential care with the skilled nursing and medical care to be provided to their residents. We will need some operational experience with the program before we can begin to evaluate the extent to which these new models of care can meet their ambitious goals.

Finally, a comment about an issue that looms for the future, beyond the immediate goals of program implementation.

As noted above, the Taskforce is directed to "gather information regarding the various ways in which existing requirements and guidelines unduly infringe on affordability of care and services," to make recommendations "ensuring that the indigent have adequate access to, and that there are a sufficient number of, enhanced assisted living residences," and to make recommendations about "developing affordable assisted living." The 1999 Governor's Program Bill on Assisted Living contained provisions which would have authorized the Commissioner of DOH to make targeted Medicaid payments for specified services provided in an assisted living setting. DOH would establish rates of payments and maximum capacities of persons eligible to receive services, subject to approval by the Division of the Budget. Such a program would have required federal approvals of appropriate Medicaid waivers. While the ALRA contains no similar provisions, the Taskforce has been asked to look into the area of financial accessibility and affordability, and to recommend possible initiatives.

Endnotes

- 1. Chapter 2 of the Laws of 2004.
- 2. SSL § 2 (21), (25), (28). 18 N.Y.C.R.R. §§ 487, 488.
- 3. 18 N.Y.C.R.R. §§ 487.7(e), 488.7(c).
- 4. 18 N.Y.C.R.R. §§ 487.4(b), 488.4(b).
- 5. SSL §§ 461, 367-h; PHL § 3614(6).

- Assisted Living in New York: Preparing for the Future—Report to the Governor and Legislature, May 1999 (available at www.health.state.ny.us/facilities/assisted living).
- 7. Senate 5982, 1999-2000 Regular Session (Governor's Program Bill).
- 8. PHL § 4650.
- 9. PHL § 4651(1).
- June 3, 2005, Dear Operator Letter (available at www.health.state.ny.us/facilities/assisted living).
- 11. PHL § 4656(1).
- 12. PHL § 4653.
- 13. PHL § 4656(2).
- 14. PHL § 4656(7).
- 15. PHL § 4656(3)(b).
- 16. PHL § 4656(6).
- 17. June 3, 2005, Dear Operator Letter (*available at* www.health.state.ny.us/facilities/assisted living).
- 18. PHL § 4657.
- 19. PHL § 4659.
- 20. PHL § 4651(13).
- 21. PHL § 4651(15).
- Enhanced Assisted Living Residence Overview (available on DOH website).
- 23. PHL § 4655(2), (4).
- 24. Olmstead v. L.C., 119 S.Ct.2176 (1999).
- 25. PHL § 4655(5).

- Special Needs Assisted Living Plan Overview and Requirements (available on DOH website).
- 27. PHL § 4658.
- Assisted Living Residence Model Residency Agreement (available on DOH website).
- 29. PHL § 4660.
- Rights of Residents in Assisted Living Residences (available on DOH website).
- 31. PHL § 4661.
- 32. SSL § 461-c(2-a).
- 33. SSL §§ 461-g, 461-h.
- 34. PHL §§ 4662, 4663.
- 35. SFL § 99-1.
- 36. Section 5 of Chapter 2, Laws of 2004.
- 37. Section 6–8 of Chapter 2, Laws of 2004.
- Application for Licensure as an Assisted Living Residence, Certification as Enhanced ALR, or Certification as Special Needs ALR (available on DOH website).

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Certificate of Need and Long-Term Care— Changes are Coming

By Jerome Levy

For nearly 40 years, the Certificate of Need process has been basically unchanged. Enacted by the passage of Article 28 of the Public Health Law in 1969, the Certificate of Need Program has provided stability and predictability for nursing homes and other health facilities included within the definition of "hospital" for Certificate of Need purposes.¹ Article 28 gave New York state one of the most detailed and vigorous Certificate of Need Programs in the United States. The law provides that, "the Department of Health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital and related services, and all public and private institutions, whether state, county, municipal incorporated or not incorporated, serving principally as facilities for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition or for the rendering of health related services shall be subject to the provisions of this article." PHL § 2800. Under the law, the requirements for the Health Department or Public Health Council ² arise in one of three situations: the establishment of a new facility, construction in an existing facility (including change in mode of service), and change of ownership in existing facilities without change in service. PHL §§ 2801-a(3), 2802. A nursing home is considered within the definition of "hospital" pursuant to § 2801.

Establishment of New Facilities

It is in the area of establishment of new facilities that the most marked changes are occurring, but change may come to the establishment of new ownerships as well. Since 1969, a person wishing to become established has had to meet three tests. The applicant has to demonstrate that there was a public need for the facility in the place proposed; that the applicants had the requisite character and competence to operate the facility; and that the project as described was financially feasible. Public Health Law § 2801-a(3).

While such events as the nursing home scandals of the late 1970s focused public attention on character and competence issues, recent emphasis has been on the issue of public need, particularly in view of developments which have highlighted the concern of the Department of Health and the Governor's Office that there is a significant excess capacity of both general hospitals and nursing homes in New York state.

Before turning to discuss public need, it will be helpful to consider some of the elements of the other two legs of the tripod, character and competence, and financial feasibility.

As noted above, the statute declares that the Public Health Council shall not approve an applicant unless it is satisfied with "the character, competence, and standing in the community," of the proposed incorporators, directors, sponsors, stockholders, members or operators. The test requires with respect to any proposed incorporator, director, sponsor, stockholder, member or operator who is already or within the past ten years has been an incorporator, director, sponsor, member, principal stockholder, principal member, or operator of any hospital, private proprietary home for adults, residences for adults, or other non-profit home for the aged or blind or a half-way house, hospice or other residential facility or institution for the care, custody or treatment of the mentally disabled, no approval shall be granted unless the Public Health Council, "shall affirmatively find by substantial evidence as to each such incorporator, director, sponsor, principal stockholder or operator that a substantially consistent high level of care is being or was being rendered in each such hospital, home, residence, half-way house, hostel, or other residential facility or institution with which such person is or was affiliated; " Regulatory authority is given to the Public Health Council, subject to the approval of the Commissioner of Health, to adopt rules and regulations to establish the criteria to be used to determine whether a substantially consistent high level of care has been rendered, with the caveat that there cannot be a finding of a substantially consistent high level of care where there had been violations of the State Hospital Code or other applicable rules or regulations that "(i) threatened to directly affect the health, safety or welfare of any patient or resident, and (ii) were recurrent or were not properly corrected."

Thus, the character and competence test creates something of a perverse result. A person who is not affiliated with any nursing home or another health institution is far more likely to pass this test than a person who is an officer or director of many facilities, since the chances of there being a problem in one or more of those facilities increases with the applicant's breadth of operating experience. In the 1970s, an individual charged with a felony withdrew as sole operator of a facility, and proposed in his stead his wife, a woman with no documented experience in management. The Court of Appeals held in *Spiegel v. Whalen*, 44 N.Y.2d 745(1978) that the Department of Health could not bar the application of the wife even where the hus-

band had a felony conviction. This rule continues to be the law today, although the Health Department has recently begun insisting that parties who apply for licensure demonstrate some experience in operation of a facility before they would recommend approval of the individual. This policy has not yet created a real conflict, since it is generally possible to find some persons within an operating group who have prior experience and a clean record. It remains to be seen whether the Health Department will attempt to bar a person without prior experience from being the sole operator or shareholder of an entity in the face of the Court of Appeals decision in *Spiegel v. Whalen*.

With respect to financial feasibility, there have been some new developments as well. Traditionally, proposed operators of nursing facilities would prepare pro forma balance sheets based on accounting projections of estimated income and expenses, demonstrating that the facility could be profitable both over an initial year and a third year of operation, which would be regarded as the "mature" period for the facility. This test was made somewhat simpler by the advent of the RUGS-2 reimbursement system in Medicaid (Medicaid provides payment for the bulk of the patient days in almost all New York state nursing facilities) in 1986. Under RUGS, it is generally possible for a new operator to project increased revenue as a result of the cost report permitted to be filed after the first twelve months of operation. 10 N.Y.C.R.R. 86-2(c). The resulting rate increase is retroactive to the commencement of the operation. Thus, it is necessary for the applicant to show in most cases—only that he has the necessary working capital to handle the cash flow in the beginning period; a retroactive rate increase usually payable within the third year will lead to demonstration of a positive cash flow. Accordingly, meeting the financial feasibility test has not been difficult for most applicants.

However, recent developments are making meeting this requirement harder, as in fact, such developments are impeding the ability to operate nursing facilities on a profitable basis. As the resident census has dropped over the last seven to eight years, the Department of Health has been scrutinizing more closely the occupancy assumptions underlying the projections submitted with applications both for new construction and change of ownership. In 2002, Department officials began asking for a "break even budget" which required applicants to determine the lowest occupancy level at which they could still break even. If the break-even occupancy percentage was higher than the percentage of occupancy actually experienced by the home prior to the proposed sale, the Department would presume that the new applicant could not be financially feasible unless there were other indications that would demonstrate an increase in revenue. Thus, a test treated as a matter of course suddenly became much more difficult

in areas where there is no recent history of high occupancy percentage.

The New World of Public Need

It is the third factor, public need, which has created the major changes sweeping the health care system. From the perspective of the Governor, the Budget Director and the State Health Department, an important element of the determination of "public need" for health facilities is its impact on the state budget. It is axiomatic that health care institutions will strive to fill vacant beds to obtain additional income to offset their largely fixed or inelastic expenses for plant costs and workers' salaries. New construction or expanded capacity will create a tendency to push to fill the new beds, with resulting increased cost to the payors. In long-term care, the most significant payor is New York State which (together with its local government units) must absorb approximately 50 percent of the total Medicaid costs. The Medicaid program state-wide pays for approximately 75 percent of the long-term care patient days (the percentage of Medicaid days is even higher in New York City). The Medicaid rate for long-term care facilities, calculated by the Department of Health according to a formula found at 10 N.Y.C.R.R. part 86-2, includes a component that (with a few exceptions for some facilities built prior to 1975) reimburses the operator with a factor in the per diem rate for the historical cost of construction of the facility. Thus, state officials are wary of approving additional facilities and, significantly, given the aging of current nursing home stock, approving replacement facilities as well.

An example makes the reasons for this reluctance apparent. A 200-bed nursing facility built in 1969 would have cost approximately \$2,000,000 to construct. Such a facility, built to meet long-discarded codes, would have small rooms which might house as many as four patients, insufficient lounge and recreational areas, woefully inadequate therapy space, and no provision for the computerbased technology needed to maintain medical record rooms and business offices. Clearly such a facility would be obsolete by today's standards. However, to replace that facility today will require construction costs of from \$40,000,000 to \$45,000,000. The bulk of such costs would be borne by the Medicaid program in its reimbursement of capital costs, over time, to the operator in the Medicaid rate. It should not be surprising, therefore, that the Department of Health imposed an informal, but nevertheless real, "moratorium" on replacement facilities in 2003. Despite some indications that the moratorium may be lifted in the near future, and the commencement of processing of a few replacement applications, the informal moratorium remains in place as of this writing.

The linking of capacity with costs to the state was the driving force behind the more formal "moratorium" imposed on applications for long-term care beds by the New York State Health Department in August 2000. This moratorium affected not only new applications to be submitted thereafter, but also pending and even approved applications which had not started construction for which public need had been found under the existing methodology.

Under the applicable regulations, 10 N.Y.C.R.R. § 709.3, public need for long-term care facilities is determined on a county-by-county basis under a formula which utilizes population data (persons over age 65) and morbidity factors to determine the number of beds required for each county or planning area.³ The number of existing or approved beds are then subtracted from this total number to yield the amount needed (if positive) or over-bedded (if negative). Need projections have been updated every few years since adopting the regulations in 1978. However, no recomputation of the data was performed between 1987, when 1993 data was projected, and 2000 when the moratorium was enacted. It becomes clear that the Department of Health was uncomfortable with the thought that as many as 30 applications which had been approved using "1993 Need" computations could come on line with consequent increases in Medicaid capital and operational cost outlays.

The moratorium was to exist until a revised public need methodology could be developed and approved. The new need methodology, which was adopted in December 2003, and became effective in the spring of 2004, did not create a radical change in the public need figures, but added a subsection providing that if the occupancy of existing facilities in the county where the new nursing facility was proposed was less than 97 percent, "there shall be a rebuttable presumption that there is no need for any additional residential health care facility beds in such planning area " 10 N.Y.C.R.R. § 709.3(f)(3). There is a provision which sets forth seven "local" factors which may be used by an applicant to attempt to overcome this rebuttable presumption. 10 N.Y.C.R.R. § 709.3(h). Notwithstanding this opportunity, almost every one of the then-pending applications, including those which had been previously approved under the former methodology, were subsequently disapproved on the basis that there was no public need for the project.

Another administrative action designed to inhibit construction of additional capacity, or replacement facilities, is the policy determination recently announced by the Department that sponsors of construction projects will need to contribute 25 percent of the total cost in "sponsor's equity," eliminating the previous practice of 90 percent financing of construction. The Federal Housing

Administration (FHA) program of financing of health facility construction contained in § 232 of the National Housing Act, 12 U.S.C.A. 1701w, which has generally been used by most non-profit and many proprietary health facility operators, permits 90% financing. FHA financing may still be employed but the Department of Health will require that no more than 75 percent of the total approved project cost be borrowed (There appear to be exceptions to this requirement which are determined on a case by case basis.). This policy has been implemented without benefit of regulatory change which would seem to be required. To date, there has been no court challenge to the Department's action.

Legislative and Executive Concern

In the fall of 2003, concern about increased Medicaid costs led the State Senate to create a "Medicaid Reform Task Force." The Task Force conducted public round table meetings and open discussions, and gathered information from *inter alia* industry and public interest sources. Among its recommendations was that there be a review of the Certificate of Need process. The report stated:

Various changes and trends in the health care system, including increased competition in the marketplace and increased instances of need for restructuring, merit a comprehensive reexamination of the structure and circumstances of the CON process in order to assure that it best meets the State's public health policy needs and the needs of the current health care environment. This examination should include the identification and correction of aspects of the process which may currently hamper the system's cost efficiency, as well as those which upon revision could otherwise further facilitate such efficiency. Senate Report, page 17.

The Senate Task Force report called for what it termed "right-sizing" of nursing homes, subject to cost-effectiveness and access tests. Right-sizing appears to be a euphemism for decertifying beds to eliminate "excess" capacity. The Senate report suggested the decertified beds could be converted to other service categories such as assisted living, long-term home health care programs or adult day care. Senate Report, page 25.

At the same time, the Governor became active by assisting in the creation of a "Health Care Reform Working Group," chaired by Steven Berger, a former Commissioner of Social Services and former Executive Director of the Port Authority of New York and New Jersey. The Working Group issued an interim report on January 13, 2004, and a final report on November 17, 2004. The January

ary report is of more concern because the key recommendation with respect to the size of the system was in the area of long-term care. The Working Group recommended an overhaul of the way the Department of Health used the CON process to actively control the system. The Working Group report, borrowing from the Senate report, employed the term "right-sizing." Pressure for cost-driven "right-sizing" continues despite the obvious demographics, noted in the Working Group's January report, which suggest an explosion in the number of persons over 65 in the next 10 to 15 years, as the "baby boomers" reach senior citizen status.

The January report demanded implementation of "a new CON review process, which is designed to incentivize providers to develop service continuums that facilitate the treatment of patients in the least restrictive, most appropriate and cost-effective settings . . . " January Report, page 15. It called for benchmarks which would "provide higher rankings (toward approval) for applications, and should include consistent high levels of quality care and patient outcomes. Additional credit should be provided (or subtracted, as the case may be), based upon the relative consistency of the proposed service mix . . . by encouraging expansion of New York State's supply of lessintense, less-restrictive care facilities, moving toward a more community and home care based approach and away from an institutional based system. These new factors should be assessed through an RFP process." Thus, the Working Group would alter the CON process from one which is applicant driven to one where applications are accepted only when government first perceives a need for additional facilities, and then invites applicants to compete to meet the need. This is a level of government management which is unprecedented in New York state.

The report also recommended change in the capital reimbursement system to replace the "pass through" system with one which would develop regional "per-bed" prices, and phase in this system over ten years to "allow for a manageable transition." Despite this clear call to reform the capital reimbursement system, the Administration has not developed legislation to modify the capital cost reimbursement for hospitals or nursing homes. As will be discussed below, the Administration's efforts seem to be focused on "right-sizing." On the subject of right-sizing, the January report estimated that there was an excess of between 6,000 to 10,000 skilled nursing beds in the state.

The final report of the Working Group, dated November 17, 2004, created substantial interest and concern in the health care community. While it focused on the "Hospital and Outpatient Industry" and recommended that "the state develop measures to reduce excess hospital capacity, and adopt alternative models for hospitals to insure access

to quality care in all communities is maintained," the report has implications for long-term care as well, particularly in view of the conclusions expressed in the January report.

With the Senate report and Working Group reports as background, the Legislature, while passing the 2005-2006 Budget Bill, acted in a fashion which could greatly alter assumptions about Certificate of Need which have been held for nearly 40 years. The Budget Bill, Chapter 61 of the Laws of 2005, created the "Commission on Health Care Facilities in the 21st Century." This is an independent Commission whose purpose is to identify and authorize closing of hospitals determined to be unnecessary or having "excessive capacity." The Commission has 18 full members, 12 appointed by the Governor, two by the Senate Majority Leader, one by the Senate Minority Leader, two by the Assembly Majority Leader and one by the Assembly Minority Leader. In addition, for these purposes the state is divided into six regions and there will be six regional members appointed for each of the regions; two by the Governor, two by the Senate Majority Leader and two by the Assembly Majority Leader. These regional Commissioners will be involved only in determinations of the particular region for which they are appointed. Stephen Berger, Chairman of the Working Group, was appointed Chair of the Commission. The Commission is currently holding a series of public hearings. It is expected to make recommendations on which hospitals in the State of New York should be closed by the end of 2006. The recommendations will have the force of law if the Governor does not veto any of them and the Legislature fails to act to modify them. This mechanism would appear to place in the hands of private individuals the ability to revoke the Certificate of Need granted pursuant to article 28 of the Public Health Law, or modify or limit the Certificate in the case of a partial closing or "right-sizing" of any given facility. Persons in Albany have likened the process to the military base closings carried out by the federal government. The assumption is the "non-political" Commission members will have greater immunity from pressure exerted by constituencies of facilities designated for closure. While the bulk of the public attention has been on the hospital sector, the Commission's charge includes nursing homes as well. It is anticipated that there will be much public involvement and political pressure to keep open any of the facilities targeted by the Commission for extinction. The Commission's authority may well be challenged in the courts by any hospital or nursing facility identified for closure or limitation. While the Task Force reports and the legislative language creating the Commission have been couched in terms of increasing quality of care, it is evident that economics is the driving force. There is no proven correlation between a facility which operates at less than full capacity and poor quality care.

In the autumn of 2005, the Commission released the guidelines under which it will determine a numerical "ranking" of hospitals and skilled nursing facilities. While there is no clear statement as to what will happen to facilities ranked at the bottom of the list, the implication is that such facilities may be targeted for elimination. The ranking criteria are:

- 1. Service to underserved populations
- 2. Availability of service
- 3. Quality of care
- 4. Economic viability
- Utilization rates
- 6. Economic impact (presumably of closure) on local area and state economy

The Commission's work is ongoing and as 2006 proceeds, we may expect its aims to come into a sharper focus. When that happens, "battle lines" will be drawn. Since much attention will be focused on the alleged excess capacity in the acute care system, it is too early to predict what the Commission's work will mean for nursing homes. Commission members have stated privately that long-term care facilities will not be exempt from the "right-sizing" requirements. Clearly, the operator of any facility targeted for closure will expect to receive "just compensation" for property taken by the action of the Commission. The Legislature's intention is unclear in this regard.

At the administrative level, the Department, at the direction of the Governor, created a "right-sizing" program initiative for nursing facilities. Facilities were offered two options to participate in this voluntary program. The first is to accept a temporary decertification of beds for a period of up to five years. This option would seem attractive to those facilities which were operating at capacities of less than 95 percent, with the result that they would not be able to bill for Medicaid bed reserve days. There are several problems with this approach. First, the Department of Health was only willing to pay 50 percent of the "bedhold" rate for the reserved days, and second, restoration of the beds could only come upon the approval of the Commissioner of Health and the Director of the Budget, neither of which was assured. Furthermore, there was no increase in the per-bed capital reimbursement to offset the loss of Medicaid capital reimbursement caused by the decertification of beds. Thus, "temporary decertification" was not a popular choice within the long-term care industry.

Second, the Department's "right-sizing" proposal included an alternative of permanent decertification of SNF beds in exchange for permission to operate a "lower

level of care" program. The alternatives included Adult Day Health Care, Long-term Home Health Care, and the Medicaid Assisted Living Program (ALP). While some of these programs may have seemed attractive alternatives to the Department, there are practical problems for any facility interested in pursuing the options, particularly the ALP. In any event, the Department reportedly had no applications submitted by the original October deadline. The deadline was extended until November 15, and there was at least one proposal submitted, but this voluntary "right-sizing" program cannot be said to be a great success.

Conclusion

The Certificate of Need program has served the people of the State of New York well for nearly 40 years. The fact that sponsors of proposed skilled nursing facilities have had to demonstrate there is a need, their operations are financially sound and that they were persons of good character has enabled regulatory officials and the public to have confidence that the health care needs of the state were being met by organizations which had satisfied such tests in the review process. It would appear that cost pressures have forced state officials to consider a drastic revision of the system in order to limit increasing costs. The effect will be to take the establishment of nursing homes out of an administrative arena and place it squarely into a clearly political playing field.⁴

Endnotes

- 1. N.Y. Public Health Law (PHL) McKinney's Title 44, § 2800 ff.
- An entity within the Department of Health authorized by PHL §§ 220 et seq.
- Under the regulations, Nassau and Suffolk counties are considered a single planning area, as are the five counties of the City of New York.
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The *Olmstead* Imperative: Judicial Interpretation of ADA and Federal-State Response

By Raul A. Tabora, Jr.

More often than not, health care policy is driven by legislative initiative and regulatory reform. Rarely does the judiciary provide a major role in reshaping the basic design of our health care system. This is especially so when it comes to the U.S. Supreme Court. As such, when a Supreme Court decision touches the core of the system, it has long-lasting consequences. This is the case with the Supreme Court's 1999 decision in *Olmstead v. L.C.*, *ex rel.*, *Zimring*.¹

Olmstead concerned a disputed provision of the Americans with Disabilities Act of 1990. A class of disabled Medicaid beneficiaries sued the State of Georgia requesting a judicial mandate to provide community-based care for the mentally ill. The class was seeking not just deinstitutionalization but the provision of necessary care for the mentally ill within the community—an affirmative mandate:

we confront the question whether the proscription of discrimination may require placement of persons with mental disabilities in community settings rather than in institutions. The answer, we hold, is a qualified yes.²

The provisions of the ADA at issue state that, "no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity."3 Regulations promulgated under these provisions expressly require that "(a) public entity shall administer services, programs, and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities."4 These regulations also mandate that a public agency "make reasonable modifications in policies, practices, or procedures when the modifications are necessary to avoid discrimination on the basis of disability, unless the public entity can demonstrate that making the modifications would fundamentally alter the nature of the service, program, or activity."5

In a plurality opinion, the Supreme Court held that mandamus relief may be available where a state or

locality fails to provide *available* community-based care to the disabled on an even keel and with a steady hand. The case was in its initial phases and no findings of fact were available. However, as a general matter, the Supreme Court noted in broad fashion:

To maintain a range of facilities and to administer services with an even hand, the State must have more leeway than the courts below understood the fundamental-alteration defense to allow. If, for example, the State were to demonstrate that it had a comprehensive, effectively working plan for placing qualified persons with mental disabilities in less restrictive settings, and a waiting list that moved at a reasonable pace not controlled by the State's endeavors to keep its institutions fully populated, the reasonable-modifications standard would be met.⁶

The impact of *Olmstead* had not been readily apparent at the time it was decided. However, from 2000 to 2003, it gained momentum and began to act as a catalyst for assessing the quality of governmental programs dealing with community-based care. As is often the case with Supreme Court decisions, its impact appears to have been greater within halls of governmental policy—through preemptive planning and the need for self-compliance—than by judicial forms of relief.

There have now been five major updates issued by the Federal Department of Health and Human Services (HHS) on compliance with *Olmstead*. In fact, HHS has consolidated *Olmstead* resources for State Medicaid Directors in a single Web site. The most recent information regarding *Olmstead* can also be found within the Office of Civil Rights' (OCR) sponsored web site at http://www.hhs.gov/ocr/mis.htm.

Along with judicial decisions interpreting *Olmstead*, these directives provide an imperative toward community-based care for disabled beneficiaries of public programs. It is up to the states and localities to assure compliance. As stated in the most recent Medicaid update:

"Medicaid home and community-based services play an increasingly critical role in enabling individuals of all ages who have a significant disability or chronic illness to live fuller, more self-directed lives in their own homes and communities than ever before."

On June 18, 2001, President Bush issued Executive Order 13217 calling upon HHS to assist states and localities in swiftly implementing the Olmstead mandate. On March 23, 2002, HHS issued a comprehensive "selfevaluation" on the status of its efforts to comply with the Olmstead directive. This report found that the three most important programs in supporting community living were (1) personal care assistance, (2) home health care and (3) home- and community-based waivers.9 More recently, the Centers for Medicare and Medicaid Services (CMS) has issued a Medicaid Director's letter allowing for data sharing regarding Long-Term Care Medical Data Set (LTC/MDS) information with respect to individuals to allow for community-based integrated settings as interpreted by Olmstead. 10 Clearly, the federal administration has sought to entrench the Olmstead mandate at the grass roots level. In the meantime, judicial trends have been not been as vigorous.

Judicial Retrenchment

The judiciary is normally loathe to direct any agency on a particular matter of policy. Judicial deference and doctrines as to the propriety of relief in such actions also temper litigation in this field. Shortly after the Supreme Court issued *Olmstead*, the Second Circuit Court of Appeals quickly limited its reach. **Rodriguez* involved the state's home care program. A class of Medicaid recipients challenged New York's failure to include "safety monitoring" as an independent task in the programs' task-based assessment of the need for personal care services. The class noted that this resulted in a failure to authorize personal care services for the mentally disabled to the same extent as that authorized for disabled individuals. The Second Circuit deflected the Class' *Olmstead* argument:

Appellees place much reliance on the Supreme Court's recent decision in *Olmstead v. L.C.,* This decision is inapposite. In *Olmstead,* the parties disputed only—and the Court addressed only—where Georgia should provide treatment, not whether it must provide it. *** The portion of the opinion most relevant to the instant dispute was the Court's statement that it was explicitly not holding that "the ADA imposes on

the States a standard of care for whatever medical services they render, or that the ADA requires States to provide a certain level of benefits to individuals with disabilities." Id. at 2188 n. 14 (internal quotation marks omitted). Olmstead does not, therefore, stand for the proposition that states must provide disabled individuals with the opportunity to remain out of institutions. Instead, it holds only that "States must adhere to the ADA's nondiscrimination requirement with regard to the services they in fact provide." Id. (emphasis added). Appellees want New York to provide a new benefit, while Olmstead reaffirms that the ADA does not mandate the provision of new benefits. Under the ADA, it is not our role to determine what Medicaid benefits New York must provide. *** Rather, we must determine whether New York discriminates on the basis of a mental disability with regard to the benefits it does provide. Because New York does not "task" safety monitoring as a separate benefit for anyone, it does not violate the ADA by failing to provide this benefit to appellees.

In June 2003, the Second Circuit revisited the field in a suit alleging, *inter alia*, *Olmstead* violations in the coordination of services for those afflicted with AIDS.¹² In *Henrietta*, the Second Circuit affirmed the granting of injunctive and equitable relief under the Rehabilitation Act and the ADA based on the admitted failures of the NYC Department of AIDS Services in coordinating care for this class of recipients. Interestingly, the city and state defended this case by arguing that disabled individuals afflicted with AIDS could no better deal with the bureaucratic system of care than those who had no disabilities, i.e., the system is equally dysfunctional for both disabled and non-disabled individuals! As noted by the Court in *Henrietta*:

Quite simply, the demonstration that a disability makes it difficult for a plaintiff to access benefits that are available to both those with and without disabilities is sufficient to sustain a claim for a reasonable accommodation.

. . .

This is not a case where the evidence has demonstrated that the plaintiffs are failing to access their full benefits even with the help of a smoothly functioning DASIS, and that those without disabilities are faring no better. Here, DASIS does not function smoothly, and the plaintiffs are unable meaningfully to access benefits. Under these circumstances, where testimonial evidence has made clear that the offered accommodation is highly ineffectual, it is no defense that others are equally unsuccessful in accessing benefits.

Decisions from other Circuit Courts of Appeals have also differed as to how far the Courts would venture in requiring Olmstead compliance. 13 More recently, the Ninth Circuit has greatly limited the reach of Olmstead relief in the context of Medicaid services. In Arc of Washington v. Braddock,14 the Circuit Court found that the State of Washington could limit the number of disabled recipients receiving Medicaid waivered services even though it was clear that many other disabled individuals would not have access based on the restricted nature of such programs. Of significance to New York's programs, this decision held that the Medicaid Act¹⁵ may be read as automatically limiting the scope of any ADA relief by setting a federally enforceable cap on funding for community-based programs. The logic behind the Ninth Circuit's decision is worth quoting at some length:

> Of course, the policy behind the ADA is a powerful one, and speaks to individuals' yearning to be as free as possible from institutionalization, with its concomitant segregation and restrictions. See, e.g., Olmstead v. L.C., ex rel., Zimring, 527 U.S. 581, 599-601, 119 S.Ct. 2176, 2186-87, 144 L.Ed.2d 540 (1999). But, the policy behind the Medicaid provision is one of experimentation, and the ADA requirements are not boundless Indeed, if they were so, they might break Medicaid's back Thus, to the extent that the statutes point in opposite directions, one of them must prevail. In this case, the Medicaid statute should receive the laurel wreath because, "[w]here there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the

priority of enactment"... If Arc were correct, the general ADA injunction against discrimination would repeal the specific Medicaid provisions for limited waiver programs. That cannot be. In so stating, we do not mean that the ADA has nothing whatsoever to say about a state's obligation to provide community-based services to the disabled. We have already held to the contrary. We merely state that the ADA does not overcome the specific cap provisions in the Medicaid statute.

Medicaid fund availability will itself encourage the use of HCBS services for the developmentally disabled, a prime goal of the ADA, but the ADA will not fundamentally upset the Medicaid program. Similarly, the states will be left with reasonable leeway in their provision of services We hold that notwithstanding the accommodation provisions of the ADA, states are permitted to use the cap provided in the Medicaid law when they utilize the Medicaid waiver program for HCBS. 16

It is also worth noting that in a succeeding decision issued on August 11, 2005, the Ninth Circuit closed the courthouse doors to any private cause of action under the equal access provisions of the Medicaid Act. ¹⁷ In addition to claims under the Medicaid Act, however, the providers and recipients in *Sanchez* brought claims under the ADA seeking *Olmstead*-style relief. The Ninth Circuit rejected these claims noting that *Olmstead* allows states to defend themselves under the ADA by showing that:

when there is evidence that a State has in place a comprehensive deinstitution-alization scheme, which, in light of existing budgetary constraints and the competing demands of other services that the State provides, including the maintenance of institutional care facilities, see *Olmstead*, 527 U.S. at 597, 119 S.Ct. 2176, is "effectively working," Id. at 605, 119 S.Ct. 2176, the courts will not tinker with that scheme. Olmstead does not require the immediate, statewide deinstutionalization of all eligible developmentally disabled persons, nor

that a State's plan be always and in all cases successful.¹⁸

New York Runs with Olmstead Ball

While the judiciary has significantly shied away from prescribing *Olmstead*-type relief, the executive branch has fastened reforms onto the *Olmstead* banner head. Aside from establishing the type of defense envisioned by the Ninth Circuit, these reforms will likely be critical to the financial survival of an effective LTC delivery system in the decades to come.

New York has traditionally been the leader among the larger states in providing a variety of options for community-based care. It has been the first to develop a "nursing home without walls" program to delay the onset of institutionalized care for the elderly (LTH-HCP). It has been the first to develop PACE demonstration programs (along with California) to test seamless long-term care delivery systems. (Now adopted by HHS via regulations.) Additionally, New York's Personal Care Assistance (PCA) program dates to the late 1970s. As a result, New York is decades ahead of other states which are just beginning to establish such programs. For example, Louisiana settled an Olmsteadrelated class action in August of 2000 by agreeing to establish a PCA program. The program is focused on those who are presently in nursing homes or at "imminent risk" of admission.

New York has also experimented in a rich array of specialized outpatient and day programs for children and adults via home- and community-based waivered projects.

Given this mix of major programs and specialized services, the question remains—has the State met its *Olmstead* mandate? The answer must be analyzed on two distinct levels. First, compliance under developing judicial decisions following *Olmstead* (e.g., assuring that systems in place are not broken and dysfunctional—*see Henrietta*, *supra*); and second, that the spirit of compliance follows the policies and objectives of the current federal administration which enforces the ADA.

Over the course of the last four years since HHS issued its *Olmstead* guidance, New York has launched a multitude of voluntary community-based initiatives known variously as NY ANSWERS, Point of Service Plans and "Right-sizing," these initiatives all lay claim to originating under the *Olmstead* imperative.

The most recent iteration of this imperative comes from the Commission on Health Care Facilities in the Twenty-First Century which launched its inaugural meeting on July 7, 2005. This Commission is part of New York's voluntary RHCF right-sizing demonstration program enacted under section 2801-e of the Public Health Law (2004). This legislation, in turn, comes on the heels of the development of "The Most Integrated Setting Coordinating Council" as part of New York's response to *Olmstead*. The grass roots details behind these efforts are beginning to materialize.

In conjunction with the Governor's Health Care Reform Working Group, the State Office for the Aging and DOH resources, the Commission has posted a background paper on the state's Long-Term Care System. The background paper reviews traditional "baby boomer" demographics and the impending drain on public resources and adds that, "(t)he impact of initiatives aimed at compliance with the U.S. Supreme Court Olmstead decision may further escalate these trends," i.e., growth of non-institutional alternatives, advances in medical technology, overall improvements in health of consumers and "increasing preference for less restrictive alternatives." The paper expressly notes:

"The Olmstead decision . . . provides an unprecedented opportunity to reshape our long-term care system to more effectively and affordably meet the needs of the disabled and elderly. Shifting the long-term care system from an institution-based to a home- and community-based system parallels the desires of the disabled and the growing elderly populations to remain at home."²⁰

Within this amalgam, the following goals and methods are set forth with regard to upcoming LTC policies:

- Improving access to LTC services (MA waiver point of service)
- 2. Promoting responsibility—MA eligibility reforms and LTC insurance affordability
- 3. Coordinating Medicare and Medicaid for dually eligible recipients
- 4. Reforming the nursing home system

When all is said and done, the Commission hopes that "options for financing long-term care without using publicly-funded services will be enhanced" and that services will be delivered in a manner which "ensures efficiency and affordability." The self-described method of achieving these goals is set forth as a "blueprint" for compliance with *Olmstead*:

- 1. Process for assessing individuals with disabilities placed in institutional settings
- 2. Identify appropriate less restrictive settings for placement
- 3. Transition a percentage to less restrictive settings based on state resources and needs of others²¹

At this point, the Commission, along with DOH, has sought to establish a cooperative relationship with those who furnish care to the elderly and disabled. Part of this cooperation has been helped along by a bottleneck of construction and renovation projects requiring Certificate of Need (CON) approval. (The background paper notes an inventory of CON applications at about \$1.4 billion.) Yet, it is still the case that those who are at the front lines in providing care will likely produce the best recommendations in assuring that a high level of quality is not jeopardized by untested initiatives. For example, as part of the "Right-sizing" initiative, LTC providers have been asked to submit requests for proposals (RFP) to temporarily decertify their capacity or to convert any excess capacity to programs focused on community care, e.g., enriched housing/assisted living, Adult Day Health Care and/or Long-Term Home Health Care. Consistent with the *Olmstead* imperative, DOH's invitation to LTC providers notes:

This demonstration program is designed to promote the development of alternative levels of care, discourage inappropriate nursing home placements, encourage the reduction of beds, generate Medicaid savings, and assist nursing homes in maintaining viability during a period of declining occupancies.

Conclusion

It is certainly in the public interest to provide appropriate LTC services in the least restrictive settings. Indeed, this concept has been handed down since the days of the Elizabethan system which is still at the ancestral core of our current model of care for the poor and disabled. What is unusual is the way in which legal precedent in the form of the Supreme Court's *Olmstead* decision has accelerated this drive and created an imperative of compliance. Whether it is the fear of

uncontrolled class action relief or the desire to place a predominant cost saving face on such compliance, few judicial decisions can lay claim to affecting public policy in such a lasting and compelling fashion.

Endnotes

- 1. 527 U.S. 521, 119 S.Ct. 2182 (1999).
- 2. Olmstead, 527 U.S. 521, 587; 119 S.Ct., 2182, 2181.
- 3. 42 U.S.C. § 12132.
- 4. 28 C.F.R. § 35.130(d).
- 5. 28 C.F.R. § 35.130(b)(7).
- 6. 527 U.S. at 607-8, 119 S.Ct. at 2189-90.
- 7. See ADA and Olmstead Decision Homepage, available at http://www.cms.hhs.gov/olmstead.
- 8. Olmstead Update No. 5 at page two, January 10, 2001.
- 9. See Delivering the Promise—Self-Evaluation to Promote Community Living, at Part II-19, available at http://www.hhs.gov/newfreedom/final/hhspart2.html.
- State Medicaid Director's Letter dated February 18, 2005, available at the OCR website.
- 11. Rodriguez v. City of New York, 197 F.3d 611 (2d Cir. 1999).
- See Henrietta D. v. Bloomberg, 331 F.3d 261 (2d Cir. 2003); cert. denied, 541 U.S. 936, 124 S.Ct. 1658, 158 L.Ed.2d 356 (2004).
- See Fisher v. Oklahoma Health Care Authority, 335 F.3d 1175 (10th Cir. 2003) (State law allowing nursing home residents to receive unlimited pharmaceuticals while limiting community based patients to a five-prescription cap held to violate community based setting requirements under Olmstead).
- 14. 403 F.3d 641 (9th Cir. 2005).
- 15. 42 U.S.C. 1396n(c) (concerning waivered programs).
- 16. Arc of Washington v. Braddock, 403 F.3d at 644-666.
- 17. 42 U.S.C 1396a(a)(30)) (See *Sanchez v. Johnson*, 416 F.3d 1051 (9th Cir. 2005).
- 18. Sanchez v. Johnson, 416 F.3d at 1068-69.
- See http://www.health.state.ny.us/facilities/rightsizing, under supplemental information: Long-Term Care, at page 2.
- 20. Id. at 3.
- 21. Id. at 13.

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A Social Ecology of Health Model in End-of-Life Decision-Making: Is the Law Therapeutic?

By Mary Beth Morrissey, JD, MPH and Bruce Jennings, MA

I. Problem Statement

Between 1976 and 1995, courts and legislatures throughout the country established the legal right to refuse life-sustaining medical treatment and developed a complex body of substantive standards and procedural rules to govern medical decision-making at the end of life. Advance directives to guide surrogate decisionmaking for patients who have lost capacity is the linchpin of this legal regime. Patients and families are now more in control of end-of-life care, and the use of hospice and palliative care services has increased. But the public has not embraced this system universally. The medical profession continues a highly technological and aggressive practice pattern. Only a small minority of individuals avail themselves of their right to execute an advance directive, and even when that is done, its instructions are not always unambiguous or always followed. Recent court rulings in a number of states, the Martin¹ case in Michigan and the Wendland² case in California, for example, indicate that the withdrawal of medically assisted nutrition and hydration remains controversial for patients who remain conscious. And the recent Schiavo³ case in Florida, while not departing from settled law in terms of the actual court rulings it occasioned, certainly indicated an intense degree of continuing social controversy over the permissibility of withholding or withdrawing life-prolonging measures.

The legal regime for end-of-life decision-making is in need of ongoing improvement and repair. Without reversing course and rejecting the important personal rights that have been established, perhaps a new strategy and a new direction are needed. We believe that the law and policy must place more emphasis on creating the type of decision-making system and environment that is conducive to good communication, continuity of care, case management and planning, and healthy dynamics within families at a time of stress and grief.

One thing at least is certainly clear. The quality and nature of end-of-life care will become more important as time goes on, not less. The demographics of aging, chronic disease, advancements in medicine and technology, changes in family structure and burgeoning health care spending impose ever-growing burdens on critical stakeholders in the end-of-life debate—individuals,

families, providers, government, the private sector, and the public. In the past, policy interventions by federal and state governments have targeted the individual as the locus of end-of-life planning and decision-making. Likewise, the role of the judiciary has been to shape legal standards that protect the rights of the individual, with or without capacity, to make health care decisions. What are the effective and affective dimensions of this process? Individualism and autonomy are the hallmarks of an incrementally formed body of end-of-life law and regulation that has had little or no reference to the social ecology of health in end-of-life decision-making. The patient, unmoored from a context of relational meaning, has been relegated to the starkest of choices a constructed death. This article seeks to apply a framework of therapeutic jurisprudence to end-of-life law and its outcomes.

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II. Legal Framework: Legacy of Quinlan to Cruzan

The main challenge facing the law of end-of-life care is to avoid the twin wrongs of burdensome over treatment or neglectful under treatment. The law is charged both to protect the interests and well-being of vulnerable individuals and to safeguard the rights of individuals to determine the course of their own medical care.

Although there are important legal rulings dating back to the early part of the 20th century on a patient's right to give or withhold consent to medical treatment,⁴ the law of end-of-life care began in the mid-1970s with the case of Karen Ann Quinlan in New Jersey.⁵ Ms. Quinlan, a young woman in her early twenties, suffered irreversible damage to the neo-cortex of her brain and fell into a state of permanent unconsciousness now

known as permanent vegetative state (PVS). After several years, her family came to the conclusion that being kept alive artificially was not morally required, was not in Ms. Quinlan's best interest, and was not what she herself would have wanted. Due to legal and moral uncertainty about such an unprecedented issue, the health care facility where Ms. Quinlan resided and her physicians would not comply, and the Quinlan family went to court seeking authorization to withdraw the ventilator that was allowing her to breathe. In a landmark decision in 1976, the New Jersey Supreme Court ruled that as her legal guardian, Mr. Quinlan had the authority to have the ventilator withdrawn. (In fact, after the ventilator was removed, Ms. Quinlan began to breathe on her own and lived in an unconscious state for another 10 years before finally dying.)

There were two legal bases for this. The first was the common-law right to bodily integrity, also developed in the body of law on informed consent. Invasive, life-extending treatments and technologies could not be imposed upon a person without consent, and must be withdrawn if refused. The second legal basis behind Quinlan was more novel at the time—a constitutional right to privacy, found by the Court in both the New Jersey and the United States Constitutions. Quinlan clearly followed in the footsteps of Griswold⁶ and Roe.⁷ In terms of both of these rights, bodily integrity and privacy, the fact that Ms. Ouinlan was unconscious and unable to decide for herself did not mean that she forfeited these rights, according to the Court. It only meant that these rights would have to be exercised by someone else—in this case her father.

In the mid-1980s a remarkably similar case unfolded in Missouri involving Nancy Beth Cruzan, who also fell into PVS after a devastating anoxic brain injury.8 Ms. Cruzan was not on a ventilator, and it was the artificial nutrition and hydration that the family wanted to withdraw. Unlike its counterpart in New Jersey a decade earlier, the Missouri Supreme Court ruled that an individual did not have the right to forgo artificial nutrition and hydration and that guardians could not act on the basis of indirect or hypothetical reasoning about what the patient's wishes would have been. Instead, if surrogates are to make such a treatment decision, it must be based on clear and convincing evidence of what the patient would have wanted. Further, if there is no clear and convincing evidence of a patient's wishes, the guardian is obligated to act in the patient's best interests, and for the Missouri Supreme Court, this meant the continuation of life and medical life support.

The Cruzan family appealed the ruling to the United States Supreme Court which issued a two-pronged ruling.9 First, the Court held that in the U.S. Constitution there is a right ("liberty interest") of the individual to refuse medical treatment, even life-prolonging medical treatment (including artificial nutrition and hydration). Second, this right to refuse treatment does not preclude the states from choosing to require clear and convincing evidence concerning the patient's own preferences before life supports could be forgone. Ms. Cruzan's feeding tube was eventually removed, and she died a short time later, but this was not a direct result of the U.S. Supreme Court ruling; it occurred only after a new trial and additional testimony had met Missouri's clear and convincing evidence standard. Many states accept a lower evidentiary standard in determining the preferences of a patient who has lost decision-making capacity. New York is like Missouri in that the clear and convincing evidence standard, upheld by the New York Court of Appeals in *In re Storar* and *In re Westchester* County Medical Center (O'Connor), is still the controlling standard for withdrawal or withholding of life-sustaining treatment from an incapacitated adult patient who has not appointed a health care agent, which health care agent is permitted by New York's Health Care Proxy Law to make decisions about artificial nutrition and hydration based upon reasonable knowledge of the patient's wishes.10

It is worth pausing to note that after Webster¹¹ (also a case arising from Missouri), a new analysis was apparent in the line of abortion cases, in which Justice Blackmun's notion of a penumbral right to privacy was replaced with Justice O'Connor's notion of avoiding undue burden on the individual's liberty interest protected under the due process clause of the Fourteenth Amendment. The end-of-life constitutional jurisprudence of this period tracked this conceptual and terminological shift, but it seemingly had little effect on the substantive outcome of these cases; either way the right of the individual (directly if competent; indirectly if lacking capacity) to refuse life-extending medical treatment was established.

The period from 1976 to 1990 was a time of legal experimentation and consolidation during which well over 100 appellate level cases involving end-of-life treatment decisions were decided in approximately half of the states. In addition to these court rulings, other legal instruments of public policy were put into place, including many state statutes establishing mechanisms for advance directives (i.e., living wills and durable powers of attorney for health care), one federal statute¹² (PSDA) designed to promote the use of advance directives

tives, and numerous administrative rulings together with guidelines and statements by medical, nursing, allied health, bar, and bioethics groups.

Taken together, this massive body of law and opinion comprises a consensus on the elements of good medical decision-making near the end of life. This consensus or framework for decision-making near the end of life contains the following points:

- Competent patients have a common-law and a constitutional right to refuse medical treatment, even if that treatment is necessary to sustain life.
- Incompetent patients have the same rights as competent patients; however, the manner in which these rights are exercised is different.
- No right is absolute; it must be balanced against countervailing rights and interests.
- The decision-making process should generally occur in the clinical setting without recourse to the courts.
- In making decisions for incompetent patients, surrogate decision-makers should apply the following standards, in descending order of preference: subjective standard, substituted judgment, best interests.
- In ascertaining an incompetent patient's preferences (the subjective standard), the patient's advance directive provides "clear and convincing evidence."
- Artificial nutrition and hydration is a medical treatment and may be withheld or withdrawn under the same conditions as any other form of medical treatment
- There is no ethical difference between withholding or withdrawing life-sustaining medical treatment.
- The right to refuse life-sustaining medical treatment does not depend on the patient's length of life expectancy or being "terminally ill."
- It is acceptable to provide pain medication sufficient to control a patient's pain even if that may foreseeably hasten the patient's death.
- Active euthanasia and assisted suicide are morally and legally distinct from forgoing life-sustaining treatment.¹³

Overall, this framework is individualistic and autonomy-respecting. Since it places such a strong emphasis on the voice of the patient in the decision-making process, one of its main goals is to continue to be guided by that voice as much as possible, even when the patient has lost decision-making capacity and can

no longer speak or decide for himself. This explains the importance that has been placed on educating patients to fill out advance directives (living wills and durable powers of attorney for health care).

However, this framework has two interrelated problems. First, it has not led to compliant behavioral change, either among ordinary citizens, who have failed in large numbers to execute advance directives, or among physicians and health care facilities, which continue to practice very aggressive forms of life-extending treatment and often fail to follow advance directives or other evidence of patient preferences in favor of more conservative or palliative treatment plans. The second problem with this framework and its underlying jurisprudence is that it is conceptually flawed and out of step with the actual experiences and values of most dying patients and their families. In a word, the law has created a decision-making process that very few individuals, aside perhaps from lawyers themselves, can understand, successfully navigate during times of extreme illness, stress, and emotional turmoil, or embrace wholeheartedly. These shortcomings are reflected in the following aspects of the legal framework:

The excessive rationalism of the framework. The framework works best for those who plan ahead for their terminal illness. Most Americans find that exceedingly hard to do. The denial of death and the reluctance of individuals to engage in advance planning remain very strong in mainstream American culture. The end-of-life framework forces people to have a particular virtue, namely, the strength of heart and will to accept mortality and the limits of what medicine can do to extend our lives.

The excessive individualism of the framework. Patient autonomy is the cornerstone, both ethically and sociologically, of the way we have approached decisions near the end of life for the past three decades. In a sense, this framework emerged from the patient's rights movement and the clash between patient autonomy and medical paternalism. Yet the reformers may have won that battle, but lost the war. The end of life is not the best time to wage battles on behalf of autonomy. Caring, family solidarity, mutual respect, love, and attentiveness to the dying person are the qualities most needed then. The end-of-life framework has been distrusting of families, and tends to make them morally invisible in the official dying process. Whether in following the patient's treatment directive (living will), or applying the substituted judgment or best interest standards, they are empty conduits of the patient's wishes. Mothers and fathers, brothers and sisters, as well as rel-

atives lose their names in bioethics and become "surrogates" or "proxies," appropriately cold terms to denote an impersonal role. A more therapeutic jurisprudential approach, defined and discussed further in the next section, would aim to create the environment for a more appropriate and healing kind of communication and shared decision-making among families and would support this process of reconciliation in the face of grief and impending loss.

The middle class cultural bias of the framework. Already suggested by the rationalism and the individualism of the framework, this framework for decision-making at the end of life does not travel well across cultures and traditions within our increasingly pluralistic society. Durable powers of attorney for health care may literally be translated into many languages, but substantively they may often be incomprehensible. Is planning and decision-making the only or the most appropriate response to the recognition that one is dying? Is everyone's first thought a concern to protect the family from being burdened? How does one respond to the suspicion, built up over a lifetime of experiencing discrimination, that advance directives are racist documents designed to limit resources offered to persons of color?

The misdiagnosis of the problem. The framework has been based on the belief that patients or surrogates must be empowered in order to avoid inappropriately aggressive and unwanted treatment at the end of life. The fundamental challenge facing end-of-life care, going forward, however, may not be individual empowerment, but rather the design and support of viable, responsive, and sustainable caring giving systems and institutions. In the modern acute care hospital, virtually everything is oriented toward the use of life-sustaining equipment and techniques, not to forgoing them. The informal culture of specialty medicine, the reward system, the institutional pressures faced by family members, the range of choices people in extremis are being asked to make—each of these factors and more make up a system that is remarkably resistant to change when confronted with an ideal, counter-cultural decision-making model, even one that is to some extent backed up by the force of law and professional ethics.

The solution to these problems is not yet clear. Perhaps a countervailing system—one oriented toward palliative and hospice care—needs to be created to give at least one real alternative to patients and families. ¹⁴ It is hard to see how anything short of this alternative system (which exists now in bits and pieces) will suffice. Until then we will continue to urge individuals to prepare for death in advance, and we will continue to require them to make a series of agonizing micro-deci-

sions in order to stay on the right pathway toward death.

III. Framework of Analysis: Therapeutic Jurisprudence

The problems with the legal framework in end-oflife decision-making, which is based on the individual right to forgo life-extending treatment, merit closer scrutiny from a therapeutic jurisprudential point of view. Therapeutic jurisprudence (TJ) has its roots in mental health law and aims critically to assess the consequences of the way the law is interpreted and applied for the law's intended beneficiaries. 15, 16 The derivation of a "therapeutic" orientation from mental health spheres has helped to define how "therapeutic" is applied in the law generally. TJ theorists suggest that the term "therapeutic" contemplates the health and mental health of the intended beneficiaries as those beneficiaries perceive them.¹⁷ To that extent, TJ rejects paternalism and refutes any attribution of paternalistic control in deeming the law and its consequences therapeutic or antitherapeutic.18 TJ casts itself as an informed decision-making model which takes account not only of the rationales for decisions, but their measurable effects, as well.

However, a TJ inquiry is not purely a pragmatic or outcomes-oriented endeavor. The framework of analysis in the TJ system is also principled and normative in its outlook. ^{19, 20} The key here is to assess the law as it is actually lived, as it impinges upon the capabilities, freedoms, and experiences of situated and relational human beings. From this perspective, the consequences of the legal framework of end-of-life care cannot be divorced from the norms and values that underlie actual end-of-life decision-making on the ground—in hospitals, long-term care facilities, and in homes.

The contribution of TJ is to permit integration of a social science system of evidence into our more traditional values-driven legal and ethical inquiries. At one end of the continuum, we have placed values of empowerment, patient autonomy and individual rights as having primacy in schema of end-of-life decisionmaking. At the other end of the continuum, we cannot ignore the outcomes of those values as they have been operationalized in end-of-life law and regulation. We may, therefore, ask if individuals and families have experienced therapeutic or positive consequences as a result of the body of law which has defined end-of-life care in the last quarter century or more. In the alternate, we may also consider whether the resulting consequences for individuals and families have been antitherapeutic. A reconciliation or balancing of values

and consequences is the end product of the TJ analysis. Should there be a conflict between values and observable consequences, there may be a resolution of such conflict in favor of values, provided that such resolution is informed by the evidence.²¹ It is conceivable that the values paradigm may be modified or altered by the evidence.

Before undertaking an examination of the evidence reports on end-of-life care and its outcomes, we need to identify the intended beneficiaries of end-of-life law and regulation. Kapp, who asks if geriatric jurisprudence is therapeutic, posits that the elderly are the principal intended beneficiaries,²² but that is perhaps too narrow a view. A social-ecological approach would probably seek to include all individuals, both elderly and non-elderly, and the members of their families or other closely bonded groups. That system may also include their surrogates and caregivers, both formal and informal, and the locus of care. Is care received at home or in an institution? Our question leads us inevitably to a multifactorial analysis of end-of-life care and its outcomes for individuals and their families as part of a broader social context.

One further comment on the conceptual orientation of this article. The perspective of therapeutic jurisprudence orients one, as we have said, toward the law as lived, the law as a social practice, and not simply (as formalists such as Hans Kelsen²³ would have it) the law as a pure logical system based on a few fundamental axioms. The notion of social ecology is essential to gain an adequate grasp on what is involved in such a perspective. TJ requires more than a traditionally individualistic conception of how law impacts on the interests and lives of persons. In biology and environmental science, ecology is the study of the systemic interaction and interdependency of various organisms among themselves and with their inorganic environment. Social ecology applies this same systems viewpoint to the complex nexus of social and cultural relations among human beings, with their extraordinarily diverse and powerful cognitive, affective, and communicative capacities.

We believe that this orientation is particularly apt to the human experience of dying and death. Here the law seeks to intervene and regulate one of the most intense, highly charged, and delicate moments in human affairs. Invested with meanings that are at once intimately personal or private and necessarily social and public, dying, or perhaps better, living near the end of life, is an ecology of a particularly complex kind. The role of law here is nearly as primeval as the role of religion, and for similar reasons: no society can be normatively indifferent to such a momentous event in the life cycle. But in the last 50 years or so, life near the end of life has been invaded and colonized by hard medical technologies. Their benefit in prolonging life can be great, but their proven potential to destroy the delicate fabric of the social ecology of life's end is also alarming. Medicine, when it was technologically impotent, once presided over the fabric of meaningful relations during the dying process—with family and friends at hand, with an opportunity to reconcile with those estranged, to forgive and to ask for forgiveness. Today, medicine and medical treatment decisions set up a dynamic that makes that ecology unstable at best, impossible at worst. If for no other reason, that is why the law must become involved with end-of-life care.

The codification of the end-of-life decision-making paradigm in the PSDA and state enabling statutes from 1990 to the present certainly provides a fertile ground for an initial TJ analysis. The policy rationales of the PSDA were ostensibly to enable individuals to access information about their rights to make health care decisions under the law, to promote execution of advance directives and their proper recognition and implementation by providers, to push statutory enactments at the state level, and to curb aggressive care at the end of life.^{24, 25} The values undergirding the legislative history of the PSDA were not a surprise—relieving pain and suffering at the end of life, reducing the burdens of care on informal caregivers, minimizing family conflict at the bedside and improving communication between individuals and their providers.^{26, 27} The real surprise is that so few of these values have been served by the PSDA and its sequelae, despite the clear policy goals.

The gap between policy and practice, the law and its consequences, values and outcomes, is at the heart of the TJ system of analysis. These gaps abound in end-oflife care. Informally, we know from anecdotal evidence that the PSDA has not delivered on its promises. More than a decade and a half after the enactment of the PSDA, roughly one in four Americans have executed advance directives. Those individuals who have bought into the bill of goods sold to the public by completing either health care proxies or living wills have in all likelihood met with a mixed range of responses in which their advance directives have either caused confusion or been more or less ignored. For many individuals, if there is an advance directive in place, they and their providers, if they even know about it, are left pondering how it will be implemented at the bedside when the critical hour arrives. Will they be overtreated or undertreated? Will they get relief from their pain and suffering? Will their surrogates carry out any semblance of

their wishes? Will their provider be receptive to dialogue with loved ones and surrogates? Will there be conflict and if so, how will it be resolved? Perhaps most importantly, will the advance directive even be relevant to the nuances of changes in the health status and the social situation of the patient that may have occurred since the advance directive was executed?

Against this backdrop of failed promises, a careful weighing of the scientific evidence of outcomes in end-of-life care is a *sine qua non* of any TJ inquiry.

IV. Reviewing the Evidence

While a comprehensive review of evidence related to end-of-life care and outcomes is beyond the scope of this article, we do wish to highlight several key reports and studies from both ends of the quantitative-qualitative evidence continuum. The Agency for Health Care Research and Quality (AHRQ) commissioned a report in 2004 that undertakes a systematic review of end-oflife care and outcomes.²⁸ In a traditional hierarchy of evidence, a systematic review is the gold standard. The segment of the AHRQ report with which we are concerned for the purposes of this article includes scientific evidence from systematic reviews, intervention studies and observational studies of health care decision-making and advance care planning in which patients and families were the primary study subjects.²⁹ The authors of the report summarize their findings in this way: "Whether improved advance care planning actually improves the experience for patients and their families has only thin and equivocal evidence."30 Lorenz and colleagues (2004) do make certain recommendations based upon their findings which are worth noting here:

- Advance care planning has to reflect changing preferences and circumstances; patients' preferences change over the course of their illness;
- When clinicians and families understand and agree with patients' preferences and prognosis, patients are more likely to experience preferred outcomes;
- Physical and psycho-social support for patients and their families is needed and can improve communication and decision-making among clinicians, patients and families.
- Interventions limited to one type of strategy and one site of care, as well as those that have few study subjects, are not likely to change care patterns or have long-term impact.³¹

Numerous studies have examined the role of providers and physicians in end-of-life care, more

specifically, provider/physician-patient communication. The classic study which is reported on by most writers in the end-of-life field is the SUPPORT study.³² The SUPPORT Principal Investigators (1995) published their five U.S. hospital-based study of patients and their physicians with the stated objectives "to improve endof-life decision-making and reduce the frequency of a mechanically supported, painful, and prolonged process of dying."33 The study population included over 9,000 patients in advanced stages of disease process, and their physicians, in two phases, one prospective observational study and a two-year controlled clinical trial with targeted interventions. Data collection methods included both medical record reviews and interviews. The most salient study findings were physicians' low-level of awareness of patient preferences, ineffective communication between physicians and patients, and physicians' aggressive treatment of patients at the end of life. In Phase II of the study, no improvement was found in physician-patient communication, physician knowledge of patient preferences, level of reported pain and aggressive treatment after the nurse intervention targeting patient-physician communication.

A follow-up SUPPORT study done by Teno et al.³⁴ was generally consistent with the above evidence. Advance directives documented in the records of seriously ill patients were found not to have any measurable effect on end-of-life care.³⁵ The researchers comment that the study findings do confirm a gap in communication between providers and patients that may not be closed by resort to advance directives.³⁶

Two studies based on more qualitative focus group and community forum-based research are worthy of note. The "Journey's End" Project of the Vermont Ethics Network³⁷ in 1996–1997 adopted a community forum approach to collecting evidence from individuals about their personal attitudes toward end-of-life care. Among the concerns identified were communication with caregivers, pain and symptom control, the locus of death and dying, and spirituality.³⁸ Participants in discussions emphasized the importance of relationships that would transform the dying experience into a "living while dying," regardless of setting.³⁹

From the physician perspective, a study of physicians using qualitative open interview methods done by DelVecchio Good and colleagues⁴⁰ reveals that physicians are also very concerned about the effectiveness of communication with patients, their families and medical teams. Physicians' narratives indicate that they experience higher levels of satisfaction with the care

they provide if their rating of communication is high.⁴¹ Physicians are also affected by their relationships with family members, not just the patient.⁴² While physicians do not commonly use the language of "good deaths" and "bad deaths" to characterize dying, they do speak to the difficult choices that need to be made in end-of-life care given the availability of life-prolonging technology, and to the process of negotiation that occurs with patients and their families in deciding "the right time to die."⁴³

Central to end-of-life care are two core principles that appear again and again in the above literature, both in the quantitative studies and the qualitative research—the value of communication and relationships. Patients and providers alike identify these elements of care as defining ones in the end-of-life experience.

V. Ethical Approaches to Health Decisionmaking and Conflict Mediation

End-of-life decision-making remains far from ideal. Many people die today while still in pursuit of unrealistic, futile hopes for cure; many deaths leave surviving family members and loved ones feeling regret as well as grief and loss. Dying becomes the object of conflict within families or between family and health professionals. People die, not in the familiar surroundings of home or a good nursing facility, but in an emergency room or intensive care unit. Equally troubling is the fact that many people still die in severe pain—not because pain cannot be treated or managed—that is very rare—but due to lack of physician training, unnecessary regulatory red tape, and financial barriers to access hospice and palliative care services.

The framework for decision-making that the law and autonomy jurisprudence has developed is not today, and perhaps never was, universally shared. People living with disabilities are sensitive to the discrimination that works against them in our society. When it comes to end-of-life care, forgoing life-sustaining treatment and the use of advance directives, they worry that an able-bodied perspective on the quality of a life marked by severe impairment and dependency is likely to be biased against continued treatment and life. A similar bias may color the advance directives of still healthy individuals fearful of future disability. Some continue to object in principle to health care decisions (especially the discontinuation of artificial nutrition and hydration) that may hasten death. Also, in our diverse and pluralistic society, many racial and ethnic minority communities have long-found the end-of-life treatment consensus foreign to their way of thinking about death

and dying, medical care, and family relationships. For those who have struggled much of their lives to obtain access to health care, discussions about refusing lifesustaining treatment are hard to fathom; such discussions make them mistrust the motives of doctors and hospitals who broach the subject.

In order to improve end-of-life care, liberation of the patient from heavy-handed medical paternalism is a necessary but far from sufficient accomplishment. Law, ethics, and policy must also come to grips with the fundamentally communal and public—not private—issues of mortality and meaning. We sometimes seem to act as though dying were solely the concern of the dying person. This vision is too narrow. What happens in dying, just as what happens in life, is shaped by and shapes social relationships. This is one of the key insights of the social ecology model and a therapeutic jurisprudence.

"Equally troubling is the fact that many people still die in severe pain—not because pain cannot be treated or managed—that is very rare—but due to lack of physician training, unnecessary regulatory red tape, and financial barriers to access hospice and palliative care services."

The challenge facing us if we would build on the end-of-life framework and improve care and decisionmaking further today is to rebuild, reinforce, and reinterpret our laws, institutions, and practices around the acknowledgment that dying is interpersonal, not strictly individualistic. Hospice has long done this, creating space for families and intimate friends to be close to the dying person; hospice also recognizes the emotional needs of those same people. The durable power of attorney for health care can likewise be understood in this light: Health care proxy decision-makers can and should take into account the dying person's concerns for those whose lives will be affected by the patient's death. For many dying persons, concern for the effects of end-of-life decisions on loved ones counts for as much, and perhaps more, than receiving medical treatment that will marginally extend life.

There are several ways that we could build upon and improve the current system. To begin with we must focus on improving communication, both horizontally, as it were, within families and vertically with physicians. Advance directives, for example, should be more

adequately and routinely factored into information and decision-making systems that physicians are comfortable with. Ways of doing this include the development of new kinds of treatment orders and documentation, electronic record keeping, and the like.

Next, the appropriate role of family members in such cases should be more easily accommodated. Without abandoning the important legal strides that reinforce a competent person's right to refuse unwanted interventions, our end-of-life care system would do better, we believe, to learn from the voices assailing it rather than hunkering down to try to preserve it from any change. The weakest link in the framework has always been the problem of how to translate the right of a competent person to refuse life-extending treatment into a right exercised by someone else on behalf of a person who no longer has decision-making capacity.

Many are now challenging not only the practicality of advance directives, but also their validity. Should a healthy or able-bodied person at a time before suffering impairment or disability be permitted to make a decision binding at a later time in his or her life? Is there sufficient continuity of values and preferences over time to be confident in following the perspective of the earlier self? What do the notions of "substituted judgment" and "best interests" really mean in practice? Many of our advance directive statutes and legal standards articulated by the courts appeal to these concepts without sufficiently examining how problematic they can be in actual end-of-life situations.

These are fundamental, ethical and philosophical issues that do not lend themselves well to new court decisions and legislation. Before we get more law, we need more deliberation, debate, and moral wisdom coming from the mechanisms of communication and education in our society. Learning how to analyze in a substantive way what the best interests of the dying patient actually are in a given case is one way to accommodate the role of all family members more fully in the decision-making process.

Surrogates named in advance directives and other family members should be given adequate information, counseling, and support. In recent years, national efforts to encourage and implement the use of advance directives in end-of-life medical care have concentrated on making individual patients aware of their rights under the law and on ensuring that both health care agents and other surrogate decision-makers (such as family members) have information about the patient's medical condition and about the patient's prior wishes and values. Not only have these two objectives proved

more difficult to fulfill than was anticipated, in and of themselves, they have proven to be insufficient to produce ethically responsible and responsive surrogate decision-making. In building a system of surrogate decision-making for end-of-life care, we need to go beyond these traditional objectives in significant ways.

We need to place more emphasis on education, counseling, and support for health care agents and other family members to improve their capacity to play this role and to improve the quality of the decisions they make. Agents are thought to be preferable to written treatment instructions (living wills) precisely because an individual on the scene has the flexibility to exercise judgment and to interpret the patient's wishes and values in light of specific (and sometimes rapidly changing) medical information about the patient's condition, treatment options, and prognosis. Written instructions cannot have these qualities of flexibility and judgment. But while we seem to expect these skills in agents and surrogates, we have done little or nothing to study the environmental conditions in the health care setting that are most conducive to them, nor have we developed protocols of education, counseling, and support aimed at enabling surrogates to engage in good decision-making. In short, we have thus far focused almost exclusively on how to empower agents to make decisions; we now must also begin to address how to enable them to make good decisions.

Moreover, hospitals and other health care facilities have an institutional and systemic responsibility and role to play in enhancing proxy decision-making. Of course, individuals and families also have a responsibility to prepare for these decisions on their own initiative. But up to now, the institutional side of the equation has been relatively neglected. More research and assessment tools are needed to assess current institutional practices and to improve them in the future. Health care professionals must become more knowledgeable about, and sensitive to, the special needs of surrogates and the special burdens of the surrogacy role. We must learn to draw on many disciplines to improve the quality of support agents and surrogates receive, including medicine and nursing, but also ethics, pastoral counseling, social work, and other sources of expertise about the full range of cognitive and emotional work surrogate decision-making entails.

Surrogacy is both a cognitive and an affective task. It involves scientific facts, normative ideas, and deep-seated emotions. While it is—and should be—primarily focused on the wishes, values, and best interests of the patient, the decisions a surrogate makes redound to

affect the surrogate himself or herself (and the entire family) as well. Families and surrogates need to have a framework within which that information has meaning and validates their own past relationship with the patient. This framework should also validate the surrogates' own sense of themselves as loving, caring, responsible people faced with life-and-death decisions in the midst of shock, loss, possibly guilt, and grief. To see surrogacy as simply an information processing task is to miss most of its human angst and drama. And yet that is the approach that many health care facilities have taken, implicitly or explicitly, by the paucity of resources they provide to agents and surrogates, by the nature and style of communication offered to them, and by the low priority most institutions give to multidisciplinary counseling and support.

No form of surrogate decision-making is immune from dispute. Instructions must be interpreted; relationships evolve. When conflicts and disagreements arise within families, independent mediation and conflict resolution services, including pastoral counseling, should be readily available in health care institutions.

VI. Conclusion

The complexity of end-of-life care defies simplistic solutions to the problems we have raised in this article. However, given both our informal information and more formal review of the evidence, we can make certain recommendations about incremental steps that may be taken to make end-of-life law and regulation more responsive to the needs of patients and families. First and foremost, there is an ongoing need to develop more extensive professional education for all professionals involved in end-of-life care, both in terms of legal and ethical content, and skills working with patients and families. This process ought to engage educators in a meaningful dialogue about how to infuse this content into educational curricula at every level of the educational experience.

Secondly, research should be funded and conducted that will give us more insight into how we can improve end-of-life care and outcomes for patients and families. An evidence base for informing policy decisions in end-of-life care will enhance our knowledge of the relationship between policy and outcomes.

Third, at the clinical level, interdisciplinary collaboration across the professions should be fostered in both informal and formal ways. Structures and methodologies of care delivery may require study and reform in order to permit a fundamental change in systems orientation from a product-driven approach to a social ecology model when it comes to end-of-life decision-making.

Finally, while end-of-life care may trigger a relational process that is more intimate and more private than most other care experiences, how we define that care necessarily involves a public discourse about shared values and meaning in our death and dying experiences. Consistent with a TJ framework of analysis, society needs to continue to work toward a common understanding of what good end-of-life decisions consist of and what environments are conducive to them so that the effects of the law will be truly therapeutic for dying persons, their families and caregivers. We suggest that this understanding ought to be the foundation of the law as we move forward into the next decade.

"Consistent with a TJ framework of analysis, society needs to continue to work toward a common understanding of what good end-of-life decisions consist of and what environments are conducive to them so that the effects of the law will be truly therapeutic for dying persons, their families and caregivers."

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Article 81 Guardianship Obstacles for Petitioning Providers: Who Should Be Proposed As Guardian? Who Should Testify?

By Alyssa M. Barreiro

Introduction

When article 81 of the Mental Hygiene Law was enacted in 1993, it moved the focus of incapacity away from medical and psychiatric diagnoses prevalent in article 77 conservatorships towards an emphasis on functional capacity of the alleged incapacitated person. At issue in article 81 is whether the Alleged Incapacitated Person (AIP) can perform the activities of daily living (ADL) such as eating, bathing, and dressing, and to what extent the AIP appreciates the nature and consequence of his or her own limitations.

Whereas conservators and committees held limited financial powers, article 81 guardians may exercise powers of the property and the person, including powers to make health care decisions and to determine the place of abode. Thus, for patients with no financial or health care agents (or agents that are breaching their fiduciary duties) hospitals and long-term care facilities throughout New York state are relying upon article 81 to meet patients' and residents' needs.

Many of these AIPs have limited or no resources, and all too often, no family or friends "willing or able" to serve as guardian. The absence of a suitable guardian is both the most common reason for the health care provider's petition and one of the most significant stumbling blocks.

A second significant stumbling block concerns disclosure and admissibility of medical evidence. Inclusion of medical information is specifically limited under article 81, as the 2004 amendments clarify.² While article 81 permits representatives of a hospital or long-term care facility to petition for guardianship, the rules of evidence apply in contested cases, thus limiting admissibility of testimony from doctors, nurses, social workers, and psychologists. These rules present unique problems for petitioning hospitals and nursing homes.

Who Should Be Proposed As Guardian?

When a hospital or long-term care facility is petitioner, a "not-for-profit corporation organized to act in such capacity, a Social Services official, or public agency authorized to act in such capacity which has a concern

for the incapacitated person," may be appointed as a guardian if they are "found by the court to be suitable to perform the duties necessary to assist the incapacitated person." In the vast majority of New York counties that do not have access to a not-for-profit corporation organized to serve as guardian, petitioners with no alternative must look to the commissioner of the Department of Social Services to serve as guardian. But as the following case illustrates, this approach often meets with resistance.

MW is an 88-year-old woman and a resident of an upstate New York nursing home. Shortly after she was admitted, the facility sought appointment of an article 81 guardian. MW, a Medicaid recipient, has no kin or friends; there was no one to consent to treatment or to marshal assets on her behalf. The commissioner of the Department of Social Services did not warmly receive the suggestion that he should serve as guardian, and prior to filing, had not consented to the appointment.

A proceeding under article 81 is commenced by filing a petition, and the court must set the date on which the order to show cause is heard no more than 28 days from the date the order to show cause is signed.⁴ But when the MW petition was filed proposing the commissioner of the County Department of Social Services as guardian, the court responded in this fashion: the order to show cause has not been executed because the Court must have a volunteer guardian before it can make any appointment.

The petition was resubmitted, amended to seek only guardianship of the person, since a Medicaid case had been opened and there were no other financial issues to resolve. A brief was submitted as to the propriety of the nominated guardian, and the impropriety of the Court's refusal to schedule a hearing, but the papers were again returned: it was the Court's policy not to serve an unwilling proposed guardian—the commissioner in this case—whether or not the individual was properly nominated. When pressed, the Court finally agreed to proceed only if the petitioner further amended the papers by eliminating the section proposing the commissioner as guardian.

The inclusion of the name, address, and telephone number of the person or persons proposed as guardian, as well as the relationship and reasons why the proposed guardian is suitable to exercise the powers, is not mandatory in the petition.⁵ Arguably, though, omission of this information causes more problems than it solves. The petitioner should thoroughly evaluate all options before proposing a Social Services official, and the rationale for that proposal and exhaustion of other alternatives should be set forth in the petition.

Article 81 practitioners recognize that, "one of the persistent problems in the area of guardianship is the difficulty finding persons who are willing to serve as guardians for persons who have no family or friends and very little in the way of assets." In these situations, "the court is left to its own devices," and some courts have looked to pro bono counsel willing to serve.

Ultimately it is up to the court to make a finding of suitability and to appoint a guardian subject to the limitations of the Mental Hygiene Law. It has been held that given the safeguards of article 81, and absent any evidence of a conflict of interest, it is an abuse of the court's discretion to deny petitioner's request for appointment.⁸ The guardian ultimately must be available, or willing, but not necessarily both.

The commissioner of the County Department of Social Services (DSS) where an AIP resides, or which manages a Medicaid case for the AIP, is a proper guardian under New York state law, though perhaps not always a willing one.

In some counties, DSS responds to the commissioner's nomination by waiving the conflict of interest flag. Counsel point to a 1996 Cayuga County case, In re Bessie C., in which the trial court appointed DSS commissioner special guardian of an 84-year-old Alzheimer's patient and Medicaid beneficiary for the purpose of exercising her right to an elective share of her husband's estate, and also appointed the commissioner guardian of the person and property. Her son appealed, and the court found that since DSS, as a preferred creditor, would seek to recoup payments from the patient's resources, a conflict existed and DSS should not be appointed with powers over property. The court observed that while the son could serve as guardian of the person, as a beneficiary of his father's estate, he too had a conflict of interest to serve as guardian of the property. The court remanded for appointment of a neutral, disinterested party.9 This was not unreasonable, because with sufficient resources available, a neutral party should not be impossible to find.

In re Patrick BB, a 65-year-old developmentally disabled man received case management services from the Office of Mental Retardation and Developmental Disabilities (OMRDD), the article 81 petitioner. This individual had a supplemental needs trust funded with money from an inheritance. OMRDD was appointed guardian by the trial court but it was reversed by the Appellate Division. Since OMRDD was both creditor and provider of services, the court found that there could be no appointment without a sufficient showing that no neutral person could be found to serve. Further, the court found OMRDD was a public agency not specifically authorized to act as guardian. The court suggested that although the New York State Association for Retarded Children (NYSARC) may also be a potential creditor, upon sufficient showing that no neutral person was available to serve, NYSARC might be an appropriate guardian.10

Article 81 specifically allows appointment of a creditor as guardian as a last resort. ¹¹ *In re Patrick BB* clearly demonstrates that the court has discretion to appoint even a creditor upon a sufficient showing that there are no better choices. Thus a DSS commissioner may be appointed despite the fact that an actual or theoretical Medicaid lien exists.

Often, a nursing home resident may have a bed in one county but a Medicaid case in another, and the counties try to shift the responsibility of guardianship from one to the other. Venue is proper in the bed county—deemed the residence of the AIP under the statute, 12 and at least in some cases judges seem more willing to appoint a commissioner from outside their own county.

Certain facts may give rise to a conflict that would directly affect a commissioner's ability to perform both his duties as commissioner and duties as guardian, such as where an AIP's Medicaid application is denied for fraudulent conveyance of assets. Absent a glaring conflict, if no other neutral person or corporation is available to act as guardian, the court should not hesitate to appoint even an unwilling commissioner as guardian.

Although Courts may suggest that a petitioner serve as guardian, the statute specifically discourages appointment of creditors and health care providers "unless the court finds that no other person or corporation is available or willing to act as guardian" 13 This is because, as the Law Revision Commission comments observe, "a service provider makes some decisions in terms of the physical and political needs of the organization and is not in a position to give his sole attention

to the best interests of the individual receiving the service."

Perhaps most significantly in the case of a petition brought on behalf of a nursing home or hospital, a corporation (other than a not-for-profit corporation specifically organized for the purpose) may not be authorized to exercise the powers necessary to assist an AIP with personal needs—only financial powers. ¹⁴ So in cases requiring health care decision-making or safe discharge planning, most long-term care providers would be ineligible to serve as guardian.

Ultimately, in the case of MW, the commissioner relented and accepted the appointment. While this was a good outcome for the petitioner, and an acceptable one for MW under the circumstances, it cannot be seen as a triumph for New York's citizens. These cases impose a financial burden on counties, and in most counties the staff is already burdened with large caseloads. While article 81 contemplated community guardian programs operating pursuant to article nine-B of the Social Services Law, or not-for-profit corporations organized for this purpose, this is not a reality in most counties, and even existing programs are hurting because of limited funding.

What can lawyers that represent nursing homes and hospitals do? Several things. First, the relief sought should be as narrowly tailored as possible to accomplish desired goals. Second, all community-based resources should be evaluated, and dual appointment should not be overlooked. Just because Mrs. Jones' nephew or neighbor may lack the resources or sophistication to marshal the residents' assets, untangle finances, and make a Medicaid application, he should not be overlooked as a possible guardian of the person. Courts favor appointment of family over strangers, and often accept the suggestion that DSS serve as guardian of the property only, with the nephew or neighbor exercising powers over the person. Third, temporary or special guardianship should be considered.¹⁵ DSS can do what it needs to do with respect to most small asset cases within a year: open the Medicaid case, redirect the income, set up the burial account, etc. An order that is self-limiting with respect to property powers, or special guardianships to handle particular transactions may often suffice.

Who Should Testify?

Once a hospital or long-term care facility has surmounted the first obstacle and nominated a proposed guardian or guardians, the petitioner must prepare for limitations on admissibility of testimony.

An AIP does not waive the CPLR privileges of confidentiality of medical records merely because a guardianship proceeding is commenced. Indeed, the petition itself need not include any, given the emphasis on functional incapacity. Nonetheless, some judges in New York have persisted in requiring medical affirmations in support of the petition. The 2004 amendment specifically prohibits this: "the court shall not require that supporting papers contain any medical information." 17

A court evaluator may apply to the court for an order permitting limited disclosure of the AIP's medical records. ¹⁸ The same records that may be reviewed by the court evaluator are not admissible as evidence at a hearing unless the AIP waives the privilege of confidentiality or affirmatively asserts her medical or mental condition at trial. ¹⁹

Patients may be incapacitated for article 81 purposes and still have sufficient capacity to object to the petition. Typical scenarios include a hospital seeking appointment of a guardian for the purpose of discharging a patient to a nursing home, or a nursing home seeking appointment of a guardian to liquidate assets in connection with a Medicaid application.

Since the medical records themselves may not be admissible, it is important to plan ahead and arrange for ADL testimony either from family members or non-medical personnel because in a contested proceeding, objection to testimony from doctors, nurses, social workers and psychologists should be sustained if the patient's medical condition is not at issue.

A court evaluator's testimony can be taken within the same privilege limitations, and, in most instances, should be taken. In *In re B.P.*, a case recently decided, the court refused to consider a court evaluator's report as part of the record because the court evaluator had not been called to testify to admit the document. ²⁰

In these cases it may be particularly important for the petitioner that the judge see the AIP. If the AIP refuses to travel to court, or cannot travel for medical or other reasons, the judge should be encouraged to hold the hearing at the facility in order to make observations of the AIP that may be incorporated into the findings. Even when the AIP is present, recent case law holds that the Fifth Amendment right to remain silent applies to the AIP in an article 81 guardianship hearing.²¹

In *In re A.G.*, at the behest of AG's treating physician, the hospital petitioned for appointment of the commissioner of Social Services as guardian for AG, a gravely ill 46-year-old man who had signed himself out of the hospital over medical advice over 16 times in

approximately 6 months. The commissioner was willing to serve and had in fact been appointed temporary guardian in the Order to Show Cause. At the hearing, although AG's relative was scheduled to testify, he failed to appear. In the community, AG had received home services, but his case manager also happened to be a registered nurse. The court sustained the objection of AG's court appointed attorney that the content of the RN's testimony was privileged. A hospital discharge planner who testified had only limited contact with the patient and could not provide extensive testimony concerning his ADL's. The commissioner's staff had insufficient contact with the patient to testify. The court had not appointed a court evaluator in the case, but rather had assigned counsel to the AIP.²² The AIP sat quietly in the courtroom; his attorney objected to his being called to testify.

In its decision, the Court held that the potential deprivation of liberty inherent in granting to others the power to make medical decisions, or to place a respondent in an institution against his or her will, is so severe as to extend to the AIP the constitutional right to remain silent during the article 81 hearing. There being insufficient evidence to establish lack of capacity, the temporary guardian was discharged and the petition was dismissed.²³

Conclusion

The unique barriers that exist for hospitals and long-term care facilities in pursuing appointment of article 81 guardians of the person and property for their patients and residents mandate careful planning in the preparation of the petition and the submission of evidence at the hearing in these cases. As every patient is unique, every article 81 petition is unique. Each has its own stakeholders, both among those entitled to notice of the proceeding, and those proposed to serve as guardians. Given that substantial liberty interests of the respondents are at risk, neither petitioning health care providers nor their attorneys should ever proceed as though these cases were routine.

Endnotes

 L. 1992 c 698 enacted Article 81 effective April 1, 1993, and repealed Articles 77 and 78.

- L. 2004 c 438 effective December 13, 2004.
- 3. N.Y. Mental Hygiene Law § 81.19(a)(2) (MHL).
- 4. MHL § 81.07 (Prior to amendment effective December 14, 2004, and when the original petition in this case was filed, this section required scheduling of the hearing within 28 days of the filing of the petition. Twenty-eight days now runs from the date that the order to show cause is signed.).
- 5. MHL § 81.08(a)(12).
- 6. MHL § 81.19; McKinney Supp. Pract. Comm. 1999.
- 7. Id. citing In re Daisy Pope, N.Y.L.J. Jan. 12, 1999 (Sup. Ct., New York Co).
- 8. In re Robinson, 272 A.D.2d 176, 709 N.Y.S.2d 170 (1st Dep't 2000). In Robinson, the court found that the trial court had abused its discretion in its appointment of the court evaluator as guardian, rather than the petitioner because there was no evidence that the petitioner had failed to care for the alleged incapacitated person properly, and there was no conflict of interest.
- In re Bessie C., 225 A.D.2d 1027, 639 N.Y.S.2d 234 (4th Dep't 1996).
- In re Patrick BB, 284 A.D.2d 636, 725 N.Y.S.2d 731 (3d Dep't 2001).
- 11. MHL § 81.19(e)(1).
- 12. MHL § 81.05(a).
- 13. MHL § 81.19(e)(2).
- 14. MHL § 81.19(a)(3).
- 15. MHL § 81.16(b).
- 16. CPLR 4504, 4507-4508.
- 17. MHL § 81.07(b)(3).
- 18. MHL § 81.09(d).
- 19. In re Rosa B.-S., 1 A.D.2d 355, 767 N.Y.S.2d 33 (2d Dep't 2003).
- In re B.P., NY Slip Op 51548(U) Sept. 27, 2005 (Sup. Ct., Bronx Co.).
- 21. *In re A.G.*, N.Y.L.J. Nov. 23, 2004, NY Slip Op 24454, 1 (Sup. Ct., Broome Co.).
- 22. Under MHL § 81.10(g), if the court appoints counsel the court can waive the appointment of the court evaluator.
- 23. In re A.G., supra.

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Appellate Division Solidifies Legal Protections for Receivers

By Jerauld E. Brydges and John M. Jennings

Recent Decision: *Niagara Mohawk Power Corporation v. Anthony Salerno* 797 N.Y.S.2d 663, 20 A.D.3d 142 (4th Dep't 2005)

In *Niagara Mohawk Power Corp. v. Salerno*, the Supreme Court Appellate Division, Fourth Department, confronted the issue of whether a creditor could hold the principal of a receiver for a nursing home, appointed pursuant to Public Health Law section 2810, personally liable for the receiver's alleged financial obligations. The creditor, Niagara Mohawk, pursued this theory after its claims against the receiver itself were stayed when the receiver filed for bankruptcy. In a victory for the defendant, the court rejected Niagara Mohawk's claims in their entirety and dismissed the case.

The dispute involved gas and electric charges allegedly incurred by the corporate receiver of a residential health care facility in Watertown, New York. The defendant, Anthony Salerno, was alleged to have owned a controlling interest in the receiver, HCA Genesis, Inc. In addition, Mr. Salerno was alleged to have owned a controlling interest in a company called MGNH, Inc., which owned the property that the facility leased.

In December 2002, Niagara Mohawk filed a breach of contract action against HCA Genesis and MGNH for their alleged failure to pay approximately \$3.1 million in unpaid utility charges, penalties, and interest. While the companies disputed Niagara Mohawk's claims, the action was stayed in September 2003 when HCA Genesis and MGNH filed voluntary petitions for relief under Chapter 11 of the Bankruptcy Code.

Niagara Mohawk then shifted tactics and commenced a lawsuit against Mr. Salerno personally, ostensibly pursuant to Public Health Law § 2808-a. This provision renders the "controlling person" of a residential health care facility jointly and severally liable with the facility itself for liabilities arising "under any provision of" article 28 of the Public Health Law.¹

In an attempt to shoehorn its claims into some alleged violation of article 28—as section 2808-a's language plainly requires—Niagara Mohawk alleged that HCA Genesis breached its fiduciary obligations and negligently administered the receivership, and that it

breached the express and implied terms of a receivership agreement between the facility and the Department of Health. At their core, however, these claims were premised upon the unpaid gas and electric bills, and therefore sounded in contract.

Niagara Mohawk may have been emboldened by the paucity of cases addressing the intended scope of section 2808-a. In fact, before this dispute, only one other reported case significantly addressed the application of this provision.² Thus, apparently relying on a perceived uncertainty about the scope of the law, Niagara Mohawk attempted to use the statute to pierce both the corporate veil and the immunities afforded to receivers under New York law.³

At the outset, the statute required Niagara Mohawk to demonstrate that the facility itself was "liable under any provision of [article 28] to any person or class of persons for damages." In attempting to fit its claims within the scope of this provision, Niagara Mohawk argued that the receiver, HCA Genesis, breached its duties, and that this breach constituted a violation of section 2810, the provision of the Public Health Law addressing the appointment of receivers. This "violation" of section 2810, Niagara Mohawk argued, constituted a violation of "any provision" of the Public Health Law sufficient to impose personal liability on Mr. Salerno under section 2808-a.

Section 2808-a, however, does not contemplate "violations" of section 2810 as the premise of "controlling person" liability. The "any provision of this article" language of section 2808-a refers to provisions that set forth the rights of nursing home patients and create causes of action against facilities for violations of those rights. Section 2801-d, for example, enumerates specific rights to which patients are entitled, and section 2803 sets forth penalties that the Department of Health (DOH) can levy against facilities for violating rules and regulations regarding patient care. Patients and the DOH, respectively, can sue to redress these violations. In fact, courts had previously recognized that it was "precisely because of the inadequacy of the existing

common-law causes of action to redress the abuse of patients in nursing homes that" these laws were enacted in the very same package of reforms that included section 2808-a. Thus, the legislature enacted section 2808-a as a *companion* measure to these patients' rights reforms in order to subject the *owners* of facilities (along with the facilities themselves) to personal liability for violations of these rights and regulations. The legislative history of section 2808-a and its related provisions make clear that these reforms were never intended to be used by creditors like Niagara Mohawk.

Given Niagara Mohawk's bald attempt to broaden the scope of section 2808-a, the defendant moved to dismiss Niagara Mohawk's complaint. The trial court denied the defendant's motion to dismiss and determined that Niagara Mohawk had stated a claim under the statute. The defendant appealed, and the Fourth Department reversed the holding of the trial court and dismissed the complaint in its entirety.

The Fourth Department recognized that Niagara Mohawk's claim turned on the scope of section 2808-a. It held that the *only* two bases for the liability of a facility under article 28 were section 2801-d(1) (for depriving residents of certain rights or benefits enumerated in the Public Health Law) and section 2803(6) (for violating regulations "pertaining to patient care by residential health care facilities").⁶ The Court concluded that, "as the legislative history makes clear, the liability of a controlling person was intended to be the same as that of the residential health care facility" under the sections set forth above.⁷

The court specifically rejected Niagara Mohawk's argument that personal liability could arise under section 2808-a from a receiver's alleged breach of its duties, even where such a breach is cast as a "violation" of section 2810. It held that section 2810(2)(d)—providing that a receiver "shall be liable only in his official capacity for injury to person and property by reason of conditions of the facility in a case where the owner would have been liable"—relates to "the *scope* of potential liability in an action against as receiver," and "does not constitute a statutorily created cause of action" from which personal liability under section 2808-a could arise. (Emphasis supplied).8

Thus, the Court held that, even if the defendant could be considered a "controlling person" under section 2808-a, "the liability of a residential healthcare facility, and thus the liability of a controlling person thereof, for the nonpayment of fees for utility services is not created by a provision of article 28." It therefore reversed the trial court and dismissed Niagara Mohawk's claims in their entirety.

The Court also discussed the only other case to significantly address the application of section 2808-a, Ocean Side Institutional Industries v. United Presbyterian Residence. 10 The parties to this dispute had each addressed Ocean Side, but had articulated vastly divergent views regarding its interpretation. The plaintiff in Ocean Side sued a receiver and its president for services that it rendered, and, like Niagara Mohawk, relied on section 2808-a to seek personal liability against the president. The Second Department dismissed the claim against the president on the narrow ground that his lack of an ownership interest in the facility precluded a finding that he was a "controlling person" under the statute. Niagara Mohawk read the case to stand for the proposition that, but for the president's lack of an ownership interest, the creditor would have had standing to pursue a claim against him under section 2808-a for the receiver's breach of its duties under section 2810. The Fourth Department rejected this characterization, observing that the Second Department never addressed the issue whether an alleged "violation" of section 2810 could create personal liability under section 2808-a.

The Fourth Department's decision in this dispute is a significant victory for receivers of residential health care facilities in New York. Niagara Mohawk's interpretation of section 2808-a would have had a significantly negative impact upon receivers. The New York State Health Facilities Association submitted an *amicus curiae* brief which detailed the negative implications of Niagara Mohawk's position. It noted that under Niagara Mohawk's interpretation of the law, "a creditor could sue any owner of a residential health care facility for any or all of the facility's obligations regardless of their source." In direct contravention of the Legislature's intent, this would "deny management-owners of residential health care facilities the protective benefits of doing business in the corporate form."

The Association also observed that the interpretation of section 2808-a set forth by Niagara Mohawk would violate public policy. Receivers of nursing homes serve a critical public function by assuming control of homes that have sought the assistance of the state pursuant to section 2810 of the Public Health Law. The limitation of liability for receivers included in this provision was meant to "encourage qualified persons to take on this important function." It would turn article 28 on its head to permit creditors to pierce this protection using section 2808-a. Moreover, this "would greatly expand the statute to impose liability upon a receiver not only for liabilities under article 28, but a broad class of undefined and unanticipated liabilities, so long as they can be categorized as a breach of fiduciary duty."

Not only does the Fourth Department's decision uphold New York public policy, but it also comports with the few cases that interpret the scope of section 2808-a. As set forth above, the Fourth Department addressed the question left unanswered by the Second Department's ruling in Ocean Side, i.e., whether creditors had standing to pursue contract claims against controlling persons under section 2808-a. The Fourth Department's decision also comports with a more recent decision rendered by the Nassau County Supreme Court. In that case, Sunrest Properties, LLC v. Sunrest Nursing Home, 11 the plaintiff landlord sought to hold the controlling person of a facility liable for the facility's alleged breach of a lease agreement. The court dismissed this claim, determining that "nothing in Public Health Law § 2808-a or any other provision of Public Health Law Article 28 grants the landlord of a nursing home standing to bring an action on behalf of its patients."12 In reaching this determination, the court described the narrow scope of 2808-a, stating that it "does not, however, create a separate or new cause of action. It makes the controlling person personally liable for damages sustained by a person asserting a claim under one of the substantive provisions of Public Health Law Article 28."13

Thus, the Fourth Department's decision in this dispute upheld settled law, legislative history, and New York public policy. Few cases have interpreted the scope of section 2808-a, and this determination was a significant blow to creditors who would seek to pierce both the corporate veil and the legal protections afforded to receivers.

Endnotes

1. The statute reads as follows:

Every person who is a controlling person of any residential health care facility liable *under any provision of this article* to any person or class of per-

sons for damages . . . shall also be liable, jointly and severally, with and to the same extent as such residential health care facility, to such person or class of persons for damages . . .

N.Y. Public Health Law § 2808-a(1) (emphasis supplied) (PHL).

- Ocean Side Institutional Industries, Inc. v. United Presbyterian Residence, 254 A.D.2d 337, 678 N.Y.S.2d 653 (2d Dep't 1998). This case will be discussed in further detail below.
- 3. See PHL § 2810(2)(d) (stating that a receiver "shall not have any liability in his personal capacity, except for gross negligence and intentional acts"). See also 149 Clinton Ave. North, Inc. v. Grassi, 51 A.D.2d 502, 506, 382 N.Y.S.2d 185, 188 (4th Dep't 1976) (a receiver who acts "in good faith, with care and prudence commensurate with the situation . . . may be immune from personal liability for losses resulting from his actions.").
- 4. PHL § 2808-a(1) (McKinney's 2002).
- Doe v. Westfall Health Care Center, Inc., 303 A.D.2d 102, 112, 755 N.Y.S.2d 769, 776 (4th Dep't 2002).
- Niagara Mohawk Power Corporation, 20 A.D.3d at 144, 797 N.Y.S.2d at 665.
- 7. Ia
- 8. Id. at 145, 797 N.Y.S..2d at 665.
- 9. Id. at 145, 797 N.Y.S.2d at 666.
- 10. 254 A.D.2d 337, 678 N.Y.S.2d 653 (2d Dep't 1998).
- 2005 N.Y. Slip Op. 51324U, 8 Misc. 3d 1028A, 20 A.D.3d at 19 (Sup. Ct. Nassau Co. 2005).
- 12. Id. at *15.
- 13. *Id.* In addition, the plaintiff in *Sunrest Properties* attempted to fit its breach of contract action into an article 28 violation by alleging that the defendant's actions "put the welfare of the residents in jeopardy." However, the court explained that, "if any of Manor's former patients' rights were violated, they, or their legal, representatives have standing to bring such an action." On that basis it dismissed the plaintiff's claim.

Jerauld E. Byrdges and John M. Jennings are associates in the commercial litigation group of Harter, Secrest & Emery's Rochester, New York, office. Mr. Brydges represented the defendant in *Niagara Mohawk v. Salerno*.

EDITOR'S SELECTED COURT DECISION

Blossom View Home v. Novello, 4 N.Y.3d 581 (2005)12797 N.Y.S.2d 370, 830 N.E.2d 268

In the Matter of Blossom View Nursing Home, appellant v. Antonia C. Novello, M.D., as Commissioner of Health of State of New York, et al., respondents.

No. 55

Court of Appeals of the State of New York.

Argued March 22, 2005.

Decided April 28, 2005.

Harter, Secrest & Emery LLP, Rochester (Thomas G. Smith of counsel), for appellant. I.

Eliot Spitzer, Attorney General, Albany (Victor Paladino, Caitlin J. Halligan, Daniel Smirlock and Nancy A. Spiegel of counsel), for respondents. I.

Neiman Ginsburg & Mairanz P.C., New York City (Marvin Neiman and Theodore T. Mairanz of counsel), for Concourse Rehabilitation & Nursing Center, Inc. and another, amici curiae.

O'Connell and Aronowitz, Albany (Cornelius D. Murray of counsel), for New York State Health Facilities Association, Inc., amicus curiae. I.

Cadwalader, Wickersham & Taft LLP, New York City (Peter G. Bergmann and Kathy H. Chin of counsel), for New York Association of Homes and Services for the Aging, amicus curiae.

Chief Judge KAYE and Judges G.B. SMITH, CIPARICK, ROSENBLATT, GRAFFEO and R.S. SMITH concur.

OPINION OF THE COURT

READ, J.

In this CPLR article 78 proceeding, petitioner Blossom View Nursing Home (Blossom) appeals from an Appellate Division order dismissing its petition seeking to bar respondents Commissioner of Health and Director of the Division of the Budget from auditing its patient review instruments (PRIs) for the years 1994 though 1996. The New York State Department of Health (DOH) did not announce its intention to commence audits of Blossom's PRIs for any of these years until August 2002, and the parties dispute whether DOH may even audit PRIs more than six years after they are filed. For the reasons that follow, we conclude that DOH is not required by its regulations to notice or commence an audit of PRIs within six years of filing; however, in light of the facts of this case, DOH may not audit Blossom's PRIs for 1995 and 1996, or use its audit of Blossom's 1994 PRIs to determine Medicaid reimbursement rates.1

I.

The Commissioner administers the state's Medical Assistance Plan (Medicaid) and sets Medicaid reimbursement rates for nursing homes, more formally called "residential health care facilities," for medical services provided to the indigent (Public Health Law §§ 2807[3], 2808[3]). Prior to 1986, the State's Medicaid per

diem reimbursement rate—the daily rate at which a facility can bill Medicaid for every Medicaid-eligible resident—was not in any way tied to the level of care required. As a result, nursing homes were thought to be discouraged from admitting individuals requiring more intensive care, who were as a consequence shunted into costly hospital beds. To reduce any rate-induced disincentive for nursing homes to provide services for individuals requiring institutional but not hospital care, DOH developed and implemented the Resource Utilization Group-II (RUG-II) case mix reimbursement methodology, effective January 1, 1986.

RUG-II is a prospective system that establishes reimbursement rates by using a nursing home's allowable costs in a base year or period,² adjusted for regional wage differentials, inflation and changes in the level of care required by its residents. RUG-II provides for reimbursement of capital and operating costs, the latter of which is composed of direct,³ indirect⁴ and noncomparable⁵ components (10 N.Y.C.R.R. 86-2.10[a][7]; [b][1][ii]; [2]).

The direct component of operating costs is based upon a patient classification system that establishes 16 RUG-II categories grouped into 5 "hierarchies," each of which is characterized by specifically diagnosed physical or mental conditions.⁶ The five hierarchies are further divided to create the 16 RUG-II categories based on the resident's functional ability to perform activities of

daily living (ADL), measured by the resident's score on an ADL index designed to reflect the need for supervision or assistance in eating, toileting and transferring (see 10 N.Y.C.R.R. Appendix 13-A).

Each of the RUG-II categories represents a different combination of the two components—condition (the hierarchy) and functional ability (the ADL)—and reflects the costs associated with caring for nursing home residents classified within the particular category, expressed as a numeric value or case mix index (CMI). Generally, the higher the CMI, the more intensive and costly the care required.

The number of a nursing home's residents classified in the various RUG-II categories determines the facility's overall CMI and thus significantly influences its per diem Medicaid reimbursement rate. Consequently, it is essential for each resident's condition and functional ability to be assessed accurately. This is accomplished by means of the PRI.

A qualified registered nurse completes the PRI, which summarizes the resident's condition, including medical diagnosis and treatments, ADLs, behavior and specialized services required during the four weeks prior to the PRI's completion. Each resident is assigned to one of the 16 RUG-II categories based on the information in the completed PRI, for which DOH has provided detailed instructions and clarification documents specifying certain "qualifiers" or criteria that must be met before any PRI question may be answered "Yes." These qualifiers take the form of time period (the four weeks before the PRI's completion), frequency (how often something needs to occur to meet the qualifier), the specific medical record documentation called for and exclusions (types of behavior or care to be disregarded when answering the question).

Nursing homes submit new PRIs electronically for all the residents in their care every six months, in accordance with a schedule set by DOH. Twice a year, at the halfway point between these "full-house" PRI filings, a nursing home must update its submission to DOH to account for new admissions and discharges (10 N.Y.C.R.R. 86-2.11[b]). To Ensure the accuracy of a nursing home's PRIs and thus the integrity of its reimbursement rates, DOH has developed a three-stage audit process. DOH has represented in this litigation that "PRI audits are performed at each facility [in the state] approximately every 18 months."

DOH sends a list of nursing homes to be audited to an independent organization with which it has contracted to accomplish this work. For Stage I audits, DOH typically provides audit forms for 40 of a nursing home's residents during the audit period, which the auditor completes independently to validate the ADL level assigned by the nursing home. The auditor usual-

ly completes a hierarchy verification sheet, or checklist, for 16 of the 40 residents, which addresses the qualifiers relevant to the resident's specific classification. Auditors principally examine a resident's medical records to complete the audit form, although they may also observe the residents whose PRIs are being audited or discuss the residents' care with nursing home staff.

The Stage I auditor returns the completed Stage I audit forms to DOH with an explanation for any differences between PRIs after auditing and as originally submitted. DOH substitutes Stage I audited PRIs for those filed by the nursing home, and also determines whether there is a statistically significant variance (a change in RUG-II category for more than 25 percent of residents whose PRIs are audited or a change in CMI for the audited residents of .05 or greater), warranting Stage II review of an additional 80 residents.⁷

A different auditor conducts the Stage II audit, which follows the same general format as the Stage I audit. The nursing home may dispute Stage I audit results with the Stage II auditor, who examines any documentation presented and either agrees with or overturns the Stage I auditor's adverse findings, referred to as "controverted items." The Stage II auditor may also seek to resolve any discrepancies between the audit findings and the nursing home's PRIs through discussion with staff or observations of residents. The Stage II auditor returns the completed Stage II audit forms to DOH, which substitutes Stage II audited PRIs for those originally filed by the nursing home, and again determines whether there is a statistically significant variance warranting a Stage III review of all remaining residents (except those in the lowest-rung RUG-II category).

Yet a third auditor conducts the Stage III audit, which follows the same general format as the Stage I and Stage II audits. The nursing home may seek to persuade the Stage III auditor to overturn controverted items from the Stage II audit. If after completion of the Stage III audit the nursing home is again found to have completed PRIs inaccurately to a statistically significant degree, DOH directs the nursing home to have its PRIs completed by an outside assessor at its own expense for at least one year (10 N.Y.C.R.R. 86-2.30[f][1][ii], [2]).8

Finally, DOH's procedures call for kicking off each stage of the audit with an entrance conference at which the auditor outlines the review's purpose, scope and timetable. During the entrance conference, the auditor must secure the nursing home's written determination as to whether an exit conference is requested. Nursing homes are entitled to an exit conference at the conclusion of each stage of the audit so long as requested at the entrance conference. At the exit conference, the auditor conveys the provisional results of the review just conducted.

On August 11, 1993, DOH's contract auditor conducted a Stage I audit of Blossom's July 1993 PRIs, and so examined records to determine the ADL levels of 40 residents and completed hierarchy checklists for 16 of them. The auditor placed 8 of these 40 residents in a different RUG-II classification, yielding a statistically significant decrease in the CMI for these 40 residents. Accordingly, a Stage II audit was scheduled for December 6, 1993.

The Stage II auditor examined the records pertaining to the remaining residents living at Blossom in July 1993 and, at Blossom's request, reassessed the Stage I auditor's findings. The Stage II auditor overturned three of the items controverted by Blossom in the Stage I audit, but agreed with the Stage I auditor as to the others. Further, the Stage II auditor concluded that PRIs for 32 additional residents were unsupported by documentation. There was an exit conference at which the auditor informed Blossom's personnel of these provisional results.

Blossom's administrator wrote a health care fiscal analyst at DOH on December 17, 1993, to complain about how the contract auditors had carried out the Stage I and II audits, and to dispute their findings. Although Blossom's resident population was too small to qualify for a Stage III audit, DOH's health care fiscal analyst nonetheless offered Blossom an additional review and thus another chance to contest Stage II audit results.

Two new outside auditors undertook this third review on March 14, 1994. The auditors examined the records of 24 patients involving 27 controverted items from the Stage II audit and agreed with the Stage II auditor on all of them, although Blossom did not know this at the time. More significantly, the auditors prepared a report "detail[ing] what occurred" during their review. This report conveys the auditors' distinct impression that Blossom's staff was at least uncooperative if not downright intimidating and hostile. Upon completing their work, the auditors told Blossom's administrator that they were finished, but needed time to compile their findings for the exit conference. When the administrator objected that the auditors "were not to leave the building until an exit interview was granted," the auditors "explained again that [they] were not prepared to do this yet and [Blossom] would hear from the [auditors' home] office."

On March 30, 1994, Blossom's attorney wrote to the health care fiscal analyst at DOH to request the exit conference. His version of the "confusion as to what exactly happened on March 14," demonstrates yet again the wisdom of Rashomon: perspective distorts reality and makes the absolute truth unknowable. According

to the attorney, during the morning session of the review there was "[a] great deal of constructive dialogue" between the auditors and Blossom's staff. In the afternoon, however, the auditors' attitude changed and they "became difficult to work with." This turn of events "dismayed" Blossom's staff "since the review, until that point, had proceeded with the smooth exchange of assistance and information." Worse yet, "the auditors left . . . without giving the nursing home staff any chance to discuss the patient records with the auditors or to see the results of the audit itself."

Blossom's attorney stated that he had since learned secondhand from DOH that the auditors "had no intention of ever returning" to conduct an exit conference, and that DOH was preparing Blossom's CMI based on the March 14, 1994, review. He protested that "without question" Blossom was "not afforded its right" to an exit conference; he requested the exit conference in advance of DOH's making any final decision regarding Blossom's CMI.

No one from DOH ever replied to Blossom's attorney's letter. Indeed, Blossom did not hear from anyone at DOH on the subject of the Stage II audit until March 28, 2001 almost seven years later when the same health care fiscal analyst responsible for affording Blossom the March 14, 1994, review wrote to offer yet another reexamination. DOH offers no explanation for this seven-year gap other than "administrative oversight."

On April 30, 2001, Blossom's attorney (not the same one who had written to DOH before), accepted the offer of another review of the July 1993 PRIs and chided DOH for not promptly providing Blossom with the exit conference requested seven years earlier. Further, he disputed DOH's right to use the audited PRIs to calculate the facility's Medicaid reimbursement rate retroactively for periods from July 1993 forward.

On July 2, 2001, the Director of DOH's Bureau of Financial Management and Information Support responded to Blossom's attorney by denying his "request" for DOH to accept Blossom's PRIs without auditing their accuracy. Noting that although DOH "sincerely regret[s] that the final adjudication of the July[] 1993 PRI review has yet to occur, we cannot agree to disregard audit findings and circumvent longstanding protocols for determining when reviews are necessary." He reiterated DOH's offer to afford Blossom a "re-review" of the 27 controverted items from the Stage II audit, and pledged to "take all steps practical to move the audit process along as expeditiously as possible for subsequent periods" so as "to make the facility current at the earliest possible date."

This second bonus review took place another eight months later, on February 22, 2002. Blossom did not question about half of the controverted items, apparently because supporting documentation for the July 1993 PRIs was in some cases no longer available. Of the remaining disputed findings, the auditors agreed with their predecessors on most, and with Blossom on only a few. As a result, the level of discrepancy between the July 1993 PRIs as submitted by Blossom and after the audit was still statistically significant. Consequently, on March 28, 2002, DOH's health care fiscal analyst directed Blossom to enter into a contract with an outside assessor approved by DOH to perform its next four rounds of PRIs (10 N.Y.C.R.R. 86-2.30[f][1][ii], [2]).

On May 3, 2002, Blossom's administrator requested a "waiver for Part 86-2.30," essentially citing DOH's tardiness in completing the audit of the July 1993 PRIs. On June 12, 2002, the Director responded, stating that it was "unclear" whether Blossom was requesting that DOH "forego processing of the audit results in total" or "rescind its instruction that the facility utilize an independent assessor for PRI submissions between July 2002 and April 2003." In either event, he denied the request.

In August 2002, DOH notified Blossom of its intention to audit Blossom's January 1994 PRIs in November 2002. Blossom's attorney wrote the Director and the fiscal health care analyst to object that DOH could "no longer conduct a timely, lawful audit of the 1994 rate period," asked DOH to withdraw its audit request and threatened a lawsuit if it did not. On October 17, 2002, the Director denied the request and stated that the audit would take place on November 18, 2002. Further, he warned, "If medical records are not made available to the auditor, we cannot presume the facility's PRIs are correct. Consequently, all issues relating to hierarchies would need to be denied and all issues relating to [ADLs] would need to be reduced to their lowest level."

When further efforts to persuade DOH to withdraw or postpone the impending audit proved futile, Blossom commenced this proceeding in Supreme Court on November 15, 2002. Blossom sought judgment declaring respondents' "announced intention" to audit 1994 PRIs to be arbitrary, capricious, irrational and contrary to state and federal law because "untimely as a matter of law;" declaring any "attempt" by respondents to audit PRIs for 1995 and 1996 to be arbitrary, capricious, irrational and contrary to state and federal law; ordering respondents to recalculate its Medicaid reimbursement rates for 1994, 1995 and 1996 using the CMI derived from the PRIs originally filed for these years; and enjoining respondents from auditing Blossom for "all periods" in 1994, 1995 and 1996.

By order to show cause dated November 18, 2002, Supreme Court granted Blossom a temporary restraining order barring respondents from auditing PRIs filed for the time period from January 1, 1994 through December 31, 1996. On January 3, 2003, Supreme Court issued a decision in Blossom's favor; on February 4, 2003, Supreme Court entered an order barring respondents from auditing Blossom's PRIs for 1994 through 1996 and directing them to recalculate Blossom's Medicaid reimbursement rates for those years in accordance with the PRIs as originally filed. The Appellate Division reversed on the law and dismissed the petition. We subsequently granted Blossom leave to appeal, and now reverse.

III.

Prior to April 1, 1983, Medicaid audit responsibilities were "inefficiently distributed among various state agencies including the Departments of Social Services and Health and the Offices of Mental Hygiene and Mental Retardation and Developmental Disabilities" (Mem. of State Exec. Dep't, reprinted in McKinney's 1983 Session Laws, at 2415, 2417). Accordingly, as of April 1, 1983, all Medicaid-related audit activities were vested in the Department of Social Services (DSS), including auditing the fiscal and statistical records and reports filed by nursing homes to support their Medicaid reimbursement rates (see L 1983, ch 83, §§ 4, 9; Social Services Law §§ 364, 368-c; 18 N.Y.C.R.R. 517.3[a][1]). DOH continued to set and adjust Medicaid rates (see Public Health Law §§ 2803[2], 2807[3], 2808) and so also, after the advent of RUG-II, undertook to review PRIs (10 N.Y.C.R.R. 86-2.30[e][3], [5]).

As of October 1, 1996, responsibility for administering the Medicaid program was shifted from DSS to DOH (see L 1996, ch 474, §§ 233–248; Social Services Law § 363-a[1]; Public Health Law § 201[1][v]). DSS's rules and regulations pertaining to transferred Medicaid functions continued in full force and effect as rules and regulations of DOH (see L 1996, ch 474, § 242). DSS retained the Medicaid audit function until April 1, 1997, when it was renamed the Department of Family Assistance, and the "Medicaid audit function pursuant to sections 364 and 368-c of the social services law" was placed with DOH (see L 1997, ch 436, part B, § 122[a], [e]).

The specific DOH and DSS regulations cited by the parties as relevant to this appeal are 10 N.Y.C.R.R. 86-2.7 (relating to audits of fiscal and statistical records and reports), promulgated by DOH in 1976; 18 N.Y.C.R.R. 517.3 (relating to audits of fiscal and statistical records and reports), promulgated by DSS in 1985; 10 N.Y.C.R.R. 86-2.30 (relating to PRIs), promulgated by DOH in 1985; and 10 N.Y.C.R.R. 415.22 (relating to patients' clinical records), promulgated by DOH in 1990.

There is considerable overlap between 10 N.Y.C.R.R. 86-2.7 and 18 N.Y.C.R.R. 517.3. This is not surprising since these provisions both address auditing

fiscal and statistical records and reports, the task transferred from DOH to DSS in 1983, and then returned from DSS to DOH in 1997. Thus, 10 N.Y.C.R.R. 86-2.7 provides that, "[a]ll fiscal and statistical records and reports shall be subject to audit. All underlying books, records and documentation which formed the basis for the fiscal and statistical reports, filed by [the nursing home] with the [State], shall be kept and maintained by the facility for a period of time not less than six years from the date of filing, or the date upon which the fiscal and statistical records were to be filed, whichever is the later date. In this respect, any rate of payment . . . will be construed to represent a provisional rate until such audit is performed and completed, at which time such rate or adjusted rate will be construed to represent the audited rate" (emphasis added).9

Similarly, 18 N.Y.C.R.R. 517.3(a)(1) specifies that for cost-based providers such as Blossom:

"[a]ll fiscal and statistical records and reports . . . used for the purpose of establishing rates . . . and all underlying books, records, documentation and reports which formed the basis for such fiscal and statistical records and reports are subject to audit. All underlying books, records and documentation which formed the basis for the fiscal and statistical reports filed by a provider with any State agency responsible for the establishment of rates of payment or fees must be kept and maintained by the provider for a period of not less than six years from the date of filing of such reports, or the date upon which the fiscal and statistical records were required to be filed, or two years from the end of the last calendar year during any part of which a provider's rate or fee was based on the fiscal and statistical reports, whichever is later [A]ny rate of payment certified or established . . . will be construed to represent a provisional rate until an audit is performed and completed, or the period within which to conduct an audit has expired without such audit having been begun or notice of such having been issued, at which time such rate or adjusted rate will be construed to represent the final rate as to those items audited" (emphasis added).

18 N.Y.C.R.R. 517.3(a)(2) concomitantly specifies that "[a]ll required fiscal and statistical reports are subject to audit for a period of six years from the date of their filing or from the date when such reports were required to be filed, whichever is later" (emphasis added); and 18 N.Y.C.R.R. 517.3(c) directs that:

"[n]otification by the department to the provider of the department's intent to audit shall toll the six-year period for record retention and audit. The department shall not notify a provider of its intent to audit more than six years from the date of filing of the fiscal and statistical reports to be audited" (emphasis added). With respect to PRIs, 10 N.Y.C.R.R. 86-2.30(e)(3) states that, "[t]he patient review form (PRI) and any underlying books, records, and/or documentation which formed the basis for the completion of such form shall be subject to review by [DOH]." Further, "[DOH], in order to ensure accuracy of the [PRI], may also conduct timely on-site observations and/or interviews of patients/residents and review of their medical records" (10 N.Y.C.R.R. 86-2.30[e][5] [emphasis added]). Finally, 10 N.Y.C.R.R. 415.22(b) requires a nursing home resident's "[c]linical records" to "be retained for six years from the date of discharge or death" (emphasis added).

As Blossom points out, PRIs and "any underlying books, records, and/or documentation which form[] the basis for [their] completion" (10 N.Y.C.R.R. 86-2.30[e][3]) in common with "fiscal and statistical records and reports" and "[a]ll underlying books, records and documentation which form[] the basis for . . . fiscal and statistical reports" (10 N.Y.C.R.R. 86-2.7; 18 N.Y.C.R.R. 517.3[a][1]), significantly influence a facility's Medicaid reimbursement rate; and six years is indisputably the period for record retention and audit of fiscal and statistical reports and their supporting documentation as well as for the retention of a resident's clinical records after discharge or death. It does not follow, however, that DOH must audit PRIs within six years of filing.

As an initial matter, PRIs are not "fiscal and statistical records and reports." The latter are the "cost reports" that nursing homes must file annually with DOH pursuant to 10 N.Y.C.R.R. 86-2.2. Nor are PRIs the "underlying books, records and documentation which form[] the basis for . . . fiscal and statistical reports," which include such things as employee payroll records, mortgage and loan documents, and purchase records. For one thing, fiscal and statistical reports must be completed in accordance with generally accepted accounting principles and certified by an accountant (10 N.Y.C.R.R. 86-2.4, 86-2.5). These requirements make no sense with respect to PRIs, which are instead subject to a three-stage audit process (10 N.Y.C.R.R. 86-2.30[e], [f], [g]) and certification by "the [facility] operator and the nurse assessor responsible for [PRI] completion" (10 N.Y.C.R.R. 86-2.30[c][3]). Further, DOH promulgated 10 N.Y.C.R.R. 86-2.30 in 1985, a time when DSS not DOH was responsible for auditing a nursing home's fiscal and statistical reports.

Courts normally "defer to an administrative agency's interpretation of its regulations if not irrational" (*In re Sylcox Nursing Home & Health Related Facility v. Axelrod*, 184 A.D.2d 986, 988 [1992], lv denied, 80 N.Y.2d 761 [1992]). Deference is especially fitting here where DOH has promulgated a separate regulation governing PRIs, which does not impose any specific deadline for PRI audits and instead simply instructs that they must be timely conducted (see 10 N.Y.C.R.R. 86-2.30[e][5]).

Nonetheless, Blossom protests that the "only rational interpretation that can be gleaned" from the relevant regulations is that 10 N.Y.C.R.R. 86-2.30(e)(5) incorporates the six-year limitations period specified in 10 N.Y.C.R.R. 86-2.7 and 18 N.Y.C.R.R. 517.3(a) and (c). Otherwise, nursing homes would be subject to financial uncertainty and would have to cope with PRI audits many years after residents had died or been discharged (which usually occurs within 2.5 years of arrival), staff had left and the rules for completing or auditing PRIs might have changed. Consequently, Blossom argues, any audit of PRIs conducted more than six years after filing places the nursing home in an untenable position. The auditor must review residents' clinical records to validate PRIs, but the nursing home may have lawfully destroyed these records for at least some of the residents in the audit population.

These are valid points. It is also true that significantly delayed or protracted PRI audits harm the public fisc by thwarting prompt recoupment of any Medicaid overpayments. As we pointed out in *In re Elcor Health Servs. v. Novello* (100 N.Y.2d 273, 280 [2003]), however, "[t]hat [DOH's] interpretation might not be the most natural reading of the regulation, or that the regulation could be interpreted in another way, does not make the interpretation irrational."

Although PRI audits are not subject to the six-year limitations period specified in 10 N.Y.C.R.R. 86-2.7 and 18 N.Y.C.R.R. 517.3(a) and (c), "timely" is not synonymous with "timeless." In this case, DOH sought to audit Blossom's January 1994 PRIs more than six years after they were filed solely because DOH neglected to wrap up its Stage II audit of Blossom's July 1993 PRIs until 2002, and PRI audits take place sequentially. Because DOH offers no better explanation than "administrative oversight" (meaning inadvertence, not supervision) for the seven-year hiatus in its nearly nine-year long audit of Blossom's July 1993 PRIs, we hold that any audit of Blossom's PRIs filed in 1995 and 1996 is untimely as a matter of law. 10 Accordingly, the order of the Appellate Division should be reversed, with costs, the proceeding converted to a declaratory judgment action and judgment granted declaring that respondents may not audit or adjust Blossom's CMI for the period January 1, 1995 through December 31, 1996, and that Blossom's Medicaid reimbursement rates for the period from January 1, 1994 through December 31, 1996 be determined by implementing the CMI as calculated using the PRIs originally filed by Blossom for 1994-1996.

Endnotes

 Blossom's request for injunctive and declaratory relief with respect to the audit of its 1994 PRIs is moot because DOH has

- already commenced and completed this audit; however, the question of this audit's use remains open for our consideration.
- For most nursing homes, 1983 is the base year. Because of a major construction and expansion project, Blossom's costs are based on the six-month period from May 1, 1991 through October 31, 1991 (10 N.Y.C.R.R. 86-2.2[e], 86-2.15). A base year is used in a prospective system to control for cost growth in excess of inflation.
- 3. Direct costs encompass the hands-on care provided to patients, such as nursing, social services, occupational therapy and physical therapy services (10 N.Y.C.R.R. 86-2.10[c][1]).
- Indirect costs include administrative services, grounds, housekeeping, food and laundry services (10 N.Y.C.R.R. 86-2.10[d][1]).
- 5. Noncomparable costs are those specific to a particular facility.
- 6. In descending order of resource utilization, these five hierarchies are heavy rehabilitation, special care, clinically complex, severe behavioral and reduced physical functioning. A nursing home resident who does not have a condition qualifying for one of the four higher hierarchies is automatically placed in the fifth, reduced physical functioning.
- For a nursing home with a population under 120, Stage II
 review encompasses all remaining residents except those in the
 lowest-rung RUG-II category, and is the last stage in the audit
 process.
- 8. For a nursing home with a population under 120, DOH would take this step after an unsatisfactory Stage II audit.
- 9. As originally promulgated in 1976, what is now 10 N.Y.C.R.R. 86-2.7 was subdivision (a) of a provision composed of subdivisions (a) through (h). On September 25, 1996, DOH proposed to amend section 86-2.7 by deleting subdivisions (b) through (h) "to eliminate obsolete language in order to recognize the transfer to [DSS in 1983] of the authority/responsibility for [nursing home] Medicaid rate audits" and to recognize that "[t]he responsibility for the Medicaid rate audit function was previously transferred to [DSS] and is authorized by DSS regulation [i.e., 18 N.Y.C.R.R. part 517]" (XVIII N.Y. Reg., Issue 39, Sept. 25, 1996, at 14). Accordingly, subdivisions (b) through (h) of 10 N.Y.C.R.R. 86-2.7 were repealed, effective January 14, 1997 (XIX N.Y. Reg., Issue 4, Jan. 29, 1997, at 10), shortly before the Legislature shifted the Medicaid audit function again, this time away from DSS to DOH (see L 1997, ch 436, part B, § 122[a], [e]).
- We also note that a nursing home's Medicaid reimbursement rates are provisional until the cost reports upon which the rates are based have been audited, or the period within which to conduct an audit has expired without either an audit having begun or a notice of audit having been issued (10 N.Y.C.R.R. 86-1.8, 86-2.7; 18 N.Y.C.R.R. 517.3[a][1]). Further, notice of intent to audit must be given within six years from the date the cost reports are filed (18 N.Y.C.R.R. 517.3[c]). A nursing home has no entitlement to Medicaid payments until these audits of cost reports have been completed, or the time for conducting them has expired without an audit having been begun or noticed (In re Cortlandt Nursing Home v. Axelrod, 66 N.Y.2d 169, 178-179 [1985]). From the record in this case, it is impossible to tell whether Blossom's Medicaid reimbursement rates for the years 1994 through 1996 were still provisional or instead were final when DOH sought to audit the January 1994 PRIs. Accordingly, we have no occasion to address in this appeal whether an audit of PRIs for time periods for which there are audited or final rates may ever be "timely" within the meaning of 10 N.Y.C.R.R. 86-2.30(e)(5).

Chief Judge KAYE and Judges G.B. SMITH, CIPAR-ICK, ROSENBLATT, GRAFFEO and R.S. SMITH concur.

Order reversed, etc.

Dietary Supplements: Balancing Consumer Choice and Safety

A Report by the New York State Task Force on Life and the Law

Executive Summary

The dietary supplement industry is a multi-billion-dollar enterprise in the United States, and dietary supplement manufacturers and distributors enjoy nearly unfettered access to consumers in New York and throughout the United States. Millions of American consumers ingest these supplements; recent surveys report nearly half of the American adult population routinely use dietary supplements.¹

The consumer turns to dietary supplements to maintain or improve health—perhaps to supplement a vitamin deficiency, lose weight, or support organ function—often believing them to be more natural, potent or pure than food or pharmaceuticals. Dietary supplements with a broad range of health claims are widely available, and the consumer may think that they have been proven effective. Dietary supplement labels need not list risks or contraindications, and the consumer may assume that supplements are safe. In each case the consumer may be wrong.

Dietary supplements are defined under federal law as products that are intended to "supplement the diet" and that contain certain "dietary ingredients" such as vitamins, minerals, herbs, and amino acids.² Dietary supplements are regulated as a class of foods, not as drugs. Like foods—and unlike drugs—most dietary supplements are not screened for safety and effectiveness by the U.S. Food and Drug Administration (FDA). Federal law does not permit dietary supplement labels to contain drug claims, such as assertions that supplements are intended to treat, diagnose, mitigate, prevent or cure diseases (absent prior government approval in specific cases). Yet the airwaves are filled with advertisements touting the health-promoting properties of dietary supplements, without mention of risk. The line between permissible and impermissible health claims for supplements is not always clear to the consumer, who naturally may misconstrue the apparent bounty of medicinal-sounding risk-free benefits.

But while many supplements may be beneficial, they are not without risks. As discussed in Chapter 3 of this report, these risks include the following:

- Certain dietary supplements have been associated with severe side effects (e.g., kava with liver failure, aristolochic acid with kidney failure);
- Certain dietary supplements have known side effects comparable to those associated with pharmaceuticals;

- Persons "self-medicating" with dietary supplements may delay necessary effective conventional medical treatment, and exacerbate disease;
- Dietary supplements may interact with common prescription and over-the-counter medications;
- The misperception that "if a little is good, more has to be better" can lead consumers to a mega-dose, risking toxic effects even from "safe" dietary supplements.

It is hoped this report is a first step toward giving New York consumers the power to make more informed choices about dietary supplements. The Task Force is recommending state-level actions because current federal oversight of dietary supplements is inadequate. Measures by New York state are warranted until the federal government implements adequate standards and enforcement for manufacturing, safety, and effectiveness.

The current scope of federal oversight of dietary supplements was established primarily by the Dietary Supplement Health and Education Act (DSHEA) of 1994.³ Among the provisions of DSHEA is an expanded definition of dietary supplements and dietary ingredients; guidelines for advertising and marketing of dietary supplements; requirements for dietary supplement product labels, and the authority for the FDA to establish good manufacturing practices for dietary supplement manufacturers.

The supplement industry has long maintained that the FDA has ample authority under DSHEA to regulate supplements and even remove them from the market when necessary. The Task Force strongly disagrees. Consider ephedra, once the dietary supplement industry's biggest moneymaker, whose sale the FDA finally restricted a decade after serious health concerns emerged. The FDA was aware of serious adverse events associated with ephedra as early as 1994.4 Yet not until 2004 did the FDA determine that ephedra posed an "unreasonable risk" of illness or injury when used under its suggested or ordinary conditions of use, and issued a regulation that essentially banned the sales of ephedra supplement products nationwide.⁵ Then in April 2005, a federal district court questioned the method by which FDA had shown unreasonable risk, and struck down the ban, at least as it applied to certain "low-dose" ephedra products.6

The lesson of ephedra is that states must be prepared to act when the FDA does not, or cannot. Indeed, a number of states, concerned by delays at the federal level, acted independently to regulate ephedra. In New York, Governor George E. Pataki signed into law a statewide ban on dietary supplements containing ephedra, effective in October 2003, citing his concern for the health and well-being of New Yorkers.⁷

The Task Force supports state action in light of the following facts, among others:

- DSHEA does not require dietary supplement manufacturers to submit safety data to the FDA before their products are sold to consumers.
- DSHEA does not require manufacturers to report adverse events associated with dietary supplements to the FDA or any other entity.
- DHSEA does not require manufacturers to include risk information on product labels, even for dietary supplements that have been associated with serious adverse events.

The federal government has the ability to address these problems. Unless and until these problems are remedied at the federal level, however, New York state action is required.

* * *

The following recommendations contemplate an Expert Committee to consider specific dietary supplements in depth, and to advise the Department of Health on provisions for ensuring the safety of New York consumers by mandating appropriate collection of data from adverse events and research, and by permitting an efficient response to evidence of risk through changes in labeling and retail restrictions as needed. An education campaign is also recommended to fill in the gaps in public information.

Recommendation I

The New York State Commissioner of Health should create an Expert Committee within the Department of Health to evaluate the safety and efficacy of dietary supplements on an ongoing basis. The Expert Committee will assess available data and make specific recommendations to the Commissioner of Health.

Data on the safety and efficacy of dietary supplements emerge continually from scientific research, adverse event reports, and other sources. Therefore, the Task Force recommends that an Expert Committee be created under the auspices of DOH to collect, evaluate, and retain all available data on the safety and efficacy of dietary supplements. The committee will also evaluate dietary supplements to determine what (if any) dan-

ger they present to the public. These evaluations will result in specific policy or regulatory recommendations to the Commissioner of Health. These recommendations might range from issuing a public advisory to banning the sale of a particular dietary supplement or dietary supplement ingredient.

The Expert Committee should consider the following policies supported by the Task Force based on current information:

i. Institute mandatory reporting by dietary supplement manufacturers and distributors of adverse events associated with dietary supplements, with continued support for voluntary reporting by consumers, health care practitioners, and others.

The FDA defines an adverse event as an incident of illness or injury that may be associated with a dietary supplement (or a range of other products), whether or not there is a clear cause/effect relationship between the adverse event and the product. A serious adverse event is one that results in death, a life-threatening illness, hospitalization, disability, congenital anomaly, or medical intervention to prevent permanent injury or damage.⁸

The FDA system for tracking adverse events related to dietary supplement use is inadequate. By its own estimate, the FDA tracks few adverse events (as few as one percent in 2000). From 1994 to 1999, the FDA received less than ten reports of adverse events from dietary supplement manufacturers. Since they are not required to collect such information, some manufacturers had no data on adverse events, while others had information that they did not share with the FDA. The supplement of the supplement is adverse events.

The Task Force believes that mandatory reporting of serious adverse events related to dietary supplement use will enhance the ability of DOH to detect patterns of illness or injury resulting from individual products that may be adulterated, contaminated, or otherwise dangerous. In addition to mandatory reporting by manufacturers and distributors doing business in New York, retailers, consumers, and health care practitioners should be encouraged to report all dietary supplement-related adverse events that occur in New York state to the FDA.

The Expert Committee should consider the following policies supported by the Task Force based on current information:

ii. Create a state-level registry of dietary supplement manufacturers and distributors doing business in New York state, or other equivalent mechanism for 1) assuring compliance with mandatory reporting of adverse events, and 2) facilitating communication with dietary supplement manufacturers and distributors.

The Expert Committee should consider the most effective means for the state to ensure compliance with mandatory adverse event reporting. One possible solution would be the establishment of a registry of those entities from which reporting is required.

The Expert Committee should consider the following policies supported by the Task Force based on current information:

iii. Obtain statutory authorization for the Commissioner of Health to require, by regulation, specific labeling of dietary supplement packaging by manufacturers on such terms as the Commissioner may deem reasonable.

Current federal dietary supplement labeling regulations fail to ensure that sufficient information is provided to facilitate consumer understanding. State-level labeling mandates can address deficits by 1) alerting consumers that particular products have not been determined to be safe and/or efficacious, and 2) informing consumers of risks that are reasonably suspected.

The Expert Committee should consider what the Task Force believes are necessary steps to ensuring the flow of accurate and sufficient information to consumers. First, the power to require dietary supplement labeling should be explicitly assigned by the Legislature to the Commissioner of Health. The Task Force recommends that the Commissioner of Health mandate that dietary supplement products that have not been proven safe during pregnancy and lactation carry a warning label. Also recommended is the labeling of specific products that have known associated risks. Finally, the Expert Committee should consider recommending that the Commissioner mandate that the labels of all dietary supplement products sold in New York state bear the FDA MedWatch toll-free telephone number to facilitate adverse event reporting.12

> The Expert Committee should consider the following policies supported by the Task Force based on current information:

iv. Obtain statutory authorization for the Commissioner of Health to ban the sale to minors or to all persons in New York State of specific dietary supplements found by the Commissioner to be unsafe. The Task Force is not recommending actions directed at specific dietary supplements. However, in the course of research, the Task Force evaluated a number of dietary supplements that might be deemed unsafe. As two initial projects in this area, the Expert Committee should (1) review the evidence for banning the sale to minors of dietary supplements that are marketed as legal alternatives to illegal drugs, and (2) review data and consider banning the sale of aristolochic acid, comfrey, and kava to all consumers in New York state.

Recommendation II

The Department of Health should undertake a major public health education campaign on dietary supplements, with variations specifically directed to different target groups.

The public education campaign will provide information about dietary supplement risks and benefits, as well as guidance for consumers in deciding whether or not to purchase dietary supplements, and how to respond to adverse events arising from dietary supplement use. Portions of the campaign should be tailored to different target audiences, including physicians and other health care professionals, complementary and alternative medicine practitioners, coaches, educators, parents, and adolescents.

* * *

These recommendations strike an appropriate balance between two legitimate state purposes: respecting consumer freedom to purchase potentially beneficial products, and protecting the health and safety of those consumers. The proposed Expert Committee on dietary supplements would develop state-level measures for tracking serious adverse events associated with dietary supplements, increasing supplement-related information available to consumers, and reacting to developing scientific literature on dietary supplements. An accompanying DOH education campaign would give consumers and health care providers a broader understanding of the potential risks and benefits associated with dietary supplements, thus allowing New Yorkers to make well-informed choices about dietary supplements.

Endnotes

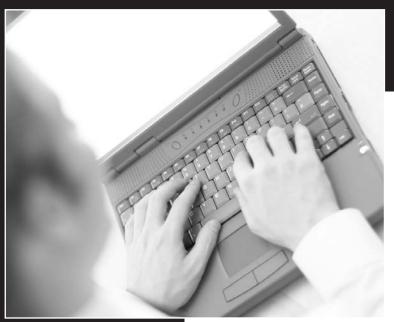
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Journal Editor's Note: This is the Executive Summary of a Report issued by the NYS Task Force on Life and the Law in October 2005. The full report is available on-line at www.health.state.ny.us/nysdoh/taskfce/. That website also provides information about obtaining paper copies of the report.

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Legal Service



Recent Programs

• The 2005 Fall Retreat. The Section's first Fall Retreat, held October 28-29 at The Sagamore on

Lake George, was a great success. The program, entitled The Medicaid Fraud and Overpayment Initiative: Representing Health on Medicaid Fraud & Abuse Law, and chaired by Jim Lytle of Manatt Phelps, was widely regarded as very informative, very timely—and often very entertaining. The Section was particularly proud of securing participation by key officials from the



Program Chair Jim Lytle

Department of Health and the Attorney General's Office. But in addition, attendees spoke highly of the social activities, the setting—even the weather. The success of the program is prompting the Section's Executive Committee to plan another retreat for next Fall.

• Fraud & Abuse Program with U.S. Attorneys. A program entitled *When Your Client's Problems Become Your Own: Meet the AUSA's,* held on September 23, was also highly praised by attendees in their post-conference surveys. That program was chaired by Robert P. Borsody of Phillips Nizer, LLP.

Upcoming Programs

- The 2006 Annual Meeting. The Section's Annual Meeting on January 26 in NYC will include a program entitled *After the Flood: Legal Issues in Public Health Emergencies*. The program will be chaired by Margaret Davino, and will include participation by both federal and state officials, as well as others with expertise on this timely topic.
- Representing Physicians and Dentists in the Disciplinary Process (April 7 in Long Island; April 28 in NYC; May 5 in Albany; May 19 in Rochester). This program is being organized by Professional Disciplinary Committee Co-Chairs Ken Larywon of Martin, Clearwater & Bell, LLP, NYC, and Carolyn Shearer of Bond, Schoneck & King, PLLC, Albany.

• Long-Term Care and the Law: Issues and Skills (May 12 in Rochester; May 12 in NYC; and May 19 in Albany). Ari Markenson of Epstein, Becker & Green, P.C., is organizing this program.

Upcoming Journal Editions

- The Spring '06 Edition. This edition of the NYSBA *Health Law Journal* will center on Legal Issues in Mental Health Care. The Special Editor is Henry Dlugacz, an attorney in NYC, who is also co-chair of the Section's Committee on Mental Health Law. Persons wishing to contribute an article should contact Mr. Dlugacz at 212-254-6470 or hd@dlugacz.com.
- The Summer/Fall '06 Edition. This edition of the *Journal* will carry articles on a variety of topics. Those who wish to submit an article should contact the *Health Law Journal* Editor, Robert N. Swidler, at 518-271-5027 or swidlerr@nehealth.com.

Other Section Activities

• Family Health Care Decisions Act—Section Representatives Testify. The Section has long supported passage of the Family Health Care Decisions Act, which would govern health care decision-making for patients who lack capacity and did not previously make their wishes known or appoint a health care agent. (See S.5807 (2005); A.5406-A (2005).) On December 8, two members of the Section's Executive Committee, Robert N. Swidler and Kathleen Burke, testified on behalf of the Section in support of the Act at a hearing held by the Assembly Health Committee.

Section Business

- Policy on Approval of Legislative Reports. The Section's Executive Committee approved the following principles regarding the approval of Legislative Reports:
 - 1. A Committee of the Health Law Section may approve a report by a simple majority of the votes cast, and may then issue the report under its own name.
 - 2. The Section's endorsement of a Committee Report requires a super majority (2/3) of the votes cast. A report endorsed by the Section may then be issued in the name of the Section.

Representing People with Disabilities,

Third Edition

Editors

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Albany, NY

Patricia W. Johnson, Esq. NYS Commission on Quality of Care for the Mentally Disabled Schenectady, NY

Nancy M. Maurer, Esq. Albany Law School Albany, NY

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Former Co-chair
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The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers (listed on the back page) or Committee Chairs for further information about these Committees.

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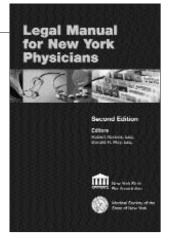
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