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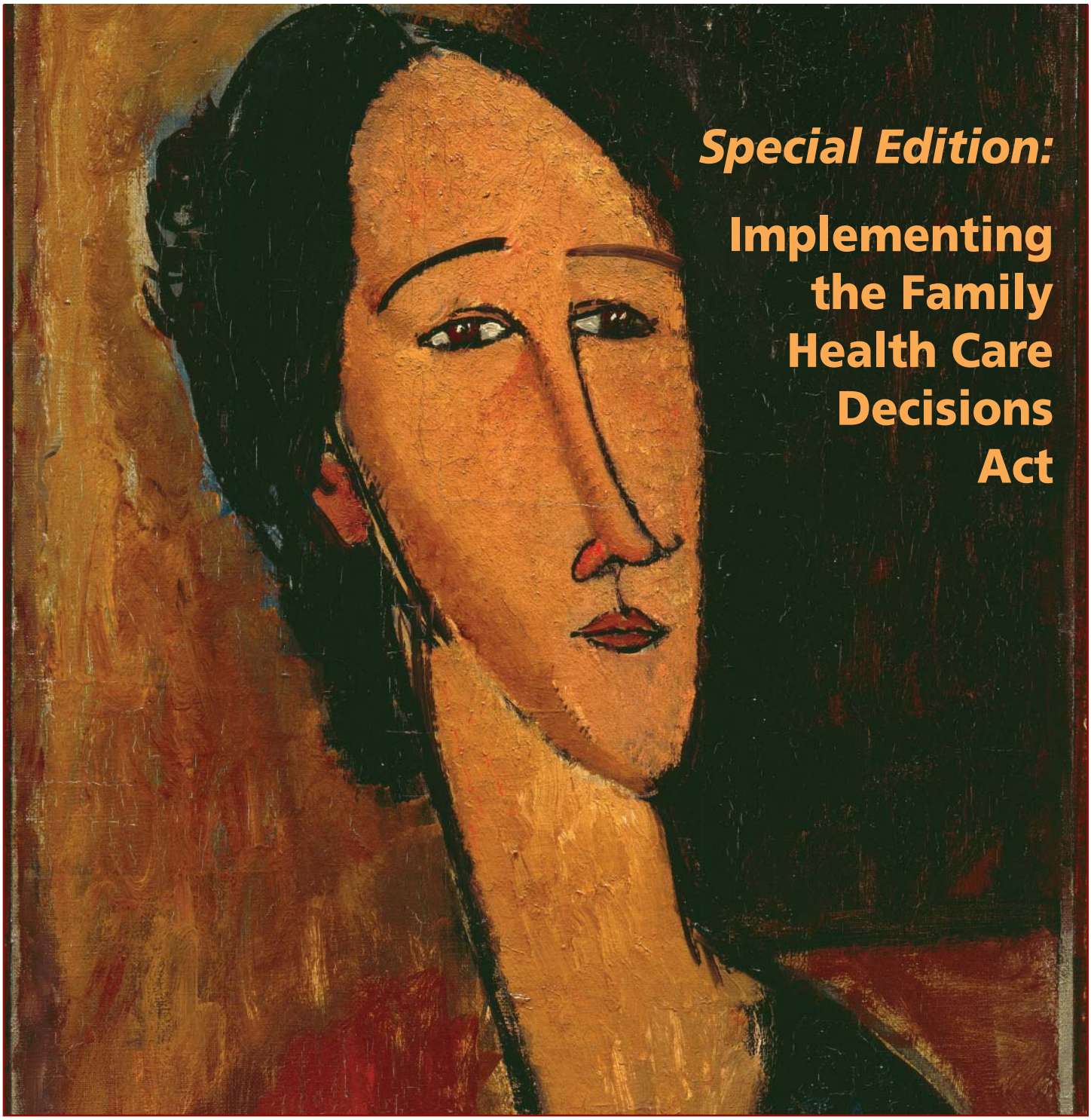
Health Law Journal

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



Special Edition:

Implementing the Family Health Care Decisions Act

Health Care Decision Making: Implementation of the Family Health Care Decisions Act, Recent Developments and Ethical Considerations

- **Friday, May 6, 2011** — **Albany**
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- **Friday, May 13, 2011** — **New York City**
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SPRING 2011

Vol. 16, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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Cover artwork:
Amedeo Modigliani (1884-1920) Untitled (portrait of a woman)
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Message from the Section Chair

I am especially proud to welcome Health Law Section members and other readers to this Special Edition of the New York State Bar Association *Health Law Journal* about the Family Health Care Decisions Act. As many of you know, the Health Law Section advocated for the enactment of the FHCDA for many years—indeed, for too many years. We supported this law because we were convinced that families in New York needed broader authority to make treatment decisions for incapable patients, and health care professionals needed clearer rules for such decisions.

Now that the FHCDA is law, we in the Health Law Section feel a special responsibility to make it work well, and serve the interests of patients. This edition is an important step toward meeting that responsibility. In the pages that follow, an impressive collection of knowledgeable and thoughtful authors share the benefit of their growing experience with the FHCDA, and offer guidance to their colleagues. Indeed they go beyond that, and in many instances offer ideas for further improvement of the laws on surrogate decision making.

I want to congratulate the authors of this Special Edition, and thank them for their commitment to achieving the promise of the FHCDA.

But our obligation to provide information to health lawyers and other about the FHCDA is not confined to this edition of the *Journal*. Section members Lawrence Faulkner of the Westchester Association for Retarded Citizens and Tracy Miller of Cadwalader, Wickersham and Taft have organized a CLE program, "Health Care Decision Making: Implementation of the Family Health Care Decisions Act, Recent Developments and Ethical Considerations." The program will be offered in:

- Albany—Friday, May 6, 2011
- New York City—Friday, May 13, 2011

An ad for the program appears on the inside cover of this issue and the program brochure can be found on the NYSBA website at www.nysba.org/health. I urge Section members and others to pick one of these locations and attend.

I would also like to take this occasion to thank and congratulate the organizers and speakers at the Annual Meeting in January. Despite a bad winter storm, there was an exceptionally large turnout for the program, which covered "Selected Developments in Health Law: The Year in Review." Audience surveys indicated that you were very pleased with the presentations. The program was co-chaired by Tracy Miller, again, and Kelly Priegnitz of Benesch, Friedlander, Coplan & Aronoff, LLP.

Please mark your calendars to join us for our Spring Member Appreciation and Networking Event on Thursday, May 12 from 6-8 p.m. at Duane Morris LLP, 1540 Broadway, 14th Floor, New York, NY 10036. Meet your colleagues, learn about what the Health Law Section has been up to over the last 12 months, and take the opportunity to get more involved. We look forward to seeing you there.

As a final note, I want to urge those Health Law Section members who have not been especially active recently to become more involved. Step forward and volunteer. Volunteer to organize a CLE, either in person or by webinar; volunteer to review or draft a legislative or regulatory proposal; volunteer to write an article for this *Journal*, or assume responsibility for an edition. Volunteer!

I wish you well, and hope you enjoy this edition.

Ari Markenson

In the New York State Courts

By Leonard M. Rosenberg

Second Circuit Court of Appeals Rules That There Is No Constitutional Right of Privacy for Fibromyalgia

Matson v. Board of Education, 2011 WL 70572 (2d Cir., 2011). Plaintiff, a music teacher at a Manhattan public school, sued the New York City Board of Education under 42 U.S.C. § 1983. Plaintiff alleged that the Board violated her constitutional right to medical privacy when it posted on a website an investigation report which disclosed that she suffers from fibromyalgia.

The investigation was commenced in response to a complaint that plaintiff was improperly claiming paid sick time when in fact she was working elsewhere. The report confirmed the accuracy of the complaint, and was posted on the website of the Special Commission of Investigation, pursuant to a city Executive Order granting authority to publish such findings. The report noted that plaintiff's application for sick leave was based on a physician's certification that she suffered from fibromyalgia, which involves neck, shoulder, and upper and lower back pain.

The Court noted that as general matter, there exists a constitutional right to privacy protecting an individual's interest in avoiding disclosure of personal matters. However, the interest in the privacy of medical information varies with the condition. Thus, confidential medical conditions are those that are "excruciatingly private and intimate…in nature…likely to provoke an intense desire to preserve one's medical condition." The Court noted that previous rulings found HIV/AIDS and transsexualism are such conditions.

Acknowledging that fibromyalgia is recognized as a disabling impairment, the Court noted that a medical acknowledgement that a disease is serious "does not give rise

ipso facto to a constitutionally protected privacy right." Fibromyalgia is neither fatal (AIDS) nor a profound psychiatric disorder (transsexualism). The privacy analysis also focuses on whether revealing one's condition would expose a person to discrimination and intolerance. Although fibromyalgia is a serious medical condition, it does not carry with it "the sort of opprobrium" sufficient to confer a constitutional right of privacy as to that condition.

Second Circuit Court of Appeals Holds That Church Amendment Provides No Private Right of Action

Cenzon-Decarlo v. Mount Sinai Hospital, 626 F.3d 695 (2d Cir., 2010). Plaintiff, an operating room nurse, sued her employer hospital under 42 U.S.C. § 300a-7(c) (a/k/a the Church Amendment). The statute provides that a recipient of federal funds may not discriminate against any employed health care personnel based on their performance of, or assistance with, a lawful abortion or sterilization procedure, or their refusal to do so based on religious beliefs or moral convictions. Plaintiff alleged that she suffered emotional harm when compelled by her supervisors to participate in an abortion procedure.

The Court held that the Church Amendment does not provide a private right of action. The Court noted that a statute which creates an individual right does not necessarily create a right of action. Relying on Supreme Court precedent, the Court noted a reluctance to infer a private remedy from either a "ban on discriminatory conduct" or a "prohibition against disbursement of public funds." Viewing the Church Amendment as a ban on conduct, the Court ruled that it confers no private right of action to enforce its terms.

The Southern District of New York Dismisses Four Related Wage and Hour Lawsuits for Plaintiffs' Failure to Properly Plead FLSA, RICO, NYLL, and Common Law Claims

Nakahata v. New York-Presbyterian Healthcare Systems, Inc., et al., 10-cv-2661 (PAC) (S.D.N.Y January 28, 2011) (Slip Copy, 200 WL 321186). Four related putative collective and class actions—by different plaintiffs against different hospitals and hospital executives—sought unpaid wages allegedly due hourly hospital employees for unspecified meal periods, breaks during which the employees worked, and training sessions. Plaintiffs also sought treble damages and attorneys' fees.

Plaintiffs alleged, on their own behalf and on behalf of the putative classes they sought to certify, that all of the named Defendants committed violations of the Fair Labor Standards Act ("FLSA"), the Racketeer Influenced and Corrupt Organizations Act ("RICO"), the New York Labor Law, and a variety of other state common-law claims. In sum, Plaintiffs (and the putative class members) alleged that they were not paid for unspecified lunch hours and breaks, training classes that they attended, and certain pre- and post-shift work and, as a result, were denied "applicable premium pay" and overtime pay.

Defendants moved for dismissal of Plaintiffs' claims, *inter alia*, on the following grounds: (1) Plaintiffs failed to state sufficient factual allegations to support the FLSA and NYLL claims; (2) the FLSA, NYLL, and common law claims are pre-empted by Section 301 of the Labor Management Relations Act (LMRA); and (3) the RICO and common claims are inadequately pleaded, legally insufficient, and preempted by the FLSA.

The District Court dismissed all four actions in their entirety. The Court held that Plaintiffs' generalized allegations did not contain sufficient facts to support Plaintiffs' claims under the FLSA or NYLL; there was no basis to name the individual hospitals within a system; there is no basis for personal liability; the RICO allegations were insufficient as a matter of law to state a claim; and the state common law claims were inadequately pleaded, duplicative of the statutory claims, and preempted by the FLSA and the LMRA.

Particular to Plaintiff's FLSA and NYLL claims, the Court held that both the FLSA and the NYLL claims require that a complaint state more than vague legal conclusions. At a minimum, the complaints must set forth the approximate number of unpaid regular and overtime hours allegedly worked. The complaints here, however, failed to lay any factual foundation for determining the viability of Plaintiffs' claims; there were no factual allegations in any of the four complaints as to the number of hours allegedly worked without compensation or when such hours were worked. Due to this failure, which is at the heart of a FLSA and NYLL claim, Plaintiff's FLSA and NYLL claims were dismissed.

The Court also held that Plaintiffs failed to state a claim under RICO. Namely, Plaintiffs failed to allege sufficient facts to satisfy the specificity requirement under Rule 9(b) of the Federal Rules of Civil Procedure in that the complaints failed to state with specificity: (i) a proper predicate act; (ii) when and where each misrepresentation was made and who made the misrepresentation; and (iii) that defendants qualify both as a person and as an enterprise within RICO.

The Court held that none of Plaintiffs' common law claims were sufficiently pleaded; the allegations are nothing more than bald assertions. Moreover, had these claims been properly pleaded, they failed for a variety of other reasons. Plaintiffs were granted leave to replead their FLSA and NYLL claims only, with the requisite specificity, and with a statement that such claims were not preempted by the collective bargaining agreements, which agreements must be attached to the amended complaints.

PHL § 2801-d Does Not Apply to Residents of State Psychiatric Hospitals

Randone v. State of New York, 910 N.Y.S.2d 355 (Court of Claims, 2010). Personal injury plaintiff, a resident of a state psychiatric hospital, sought to assert a damage claim under Public Health Law ("PHL") § 2801-d, which authorizes a private right of action by patients of residential health care facilities for violations of rights set forth in PHL § 2803-c (Rights of Patients in Certain Medical Facilities).

The Court held that PHL Article 28, by definition, excludes psychiatric facilities under the jurisdiction of the Office of Mental Health ("OMH"); and that the term Residential Health Care Facility refers to nursing homes and related facilities under the jurisdiction of the Department of Health. Because a state psychiatric hospital is under the jurisdiction of OMH, and primarily provides services for the treatment of mental disability, plaintiff had no claim under PHL § 2801-d.

No Hospital Liability for Employees Who Follow Directions of Private Attending Physician

Sela v. Katz, 911 N.Y.S.2d 112 (2d Dep't, 2010). In this medical malpractice suit, the Court affirmed summary judgment dismissal of plaintiff's claims against the hospital. Those claims were based on injuries allegedly sustained from excessive tourniquet pressure applied by hospital employees (operating room staff) during surgery, at the direction of plaintiff's private physician, who was not a hospital employee.

The Court held that a hospital employee's undertaking the ministerial task of recording a patient's informed consent does not transfer to the hospital the duty to obtain such consent, thus there is no claim against the hospital for breach of that duty. Moreover, hospitals are shielded from liability when their employees follow orders of a private attending physician unless the orders are so clearly outside standard practices that prudence requires inquiry by the employees (not the case here).

Court Upholds Physician's License Revocation and $50,000 Fine

Patin v. State Board for Professional Medical Conduct, 911 N.Y.S.2d 184 (3d Dep't, 2010). Physician sought to annul revocation of medical license. After a hearing, 28 of 32 charges against physician were sustained, including negligence, incompetence, practicing medicine in a fraudulent manner, filing false reports, failing to maintain accurate records, ordering unwarranted tests, and engaging in conduct evincing moral unfitness. Petitioner was fined $50,000 and his license was revoked.

The Court denied the physician's application, noting expert testimony in the record that, among other things, the physician's medical records showed a pattern of stating only a diagnosis with no elaboration of symptoms, history, follow-up or physical findings. The Court also held that finding of fraudulent billing was sufficient to support the charge of moral unfitness.

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

As this edition heads to press, and with just a few hours left before the commencement of the 2011-12 fiscal year, the New York State Legislature enacted a comprehensive set of recommendations relating to the State's Medicaid program. These proposals define how the Administration seeks to enact over $2 billion in State-share Medicaid spending cuts, the budget reduction target that was set forth in Governor Andrew Cuomo's Executive Budget proposal submitted on February 1. The specific means by which the State might achieve that spending reduction target had been left to the Medicaid Redesign Team (MRT), which submitted its recommendations to the Governor at the end of February. With the introduction of its thirty-day amendments, the Administration fulfilled the necessary additional step of translating the MRT recommendations into legislative proposals—as Governor Cuomo noted when he received the recommendations of the MRT, "we just filled in the blank."

The proposals now passed by the Legislature would enact sweeping changes to the Medicaid program in New York, even after facing close scrutiny by the Legislature in the relatively short period of time between the submission of these proposals and the April 1 budget adoption deadline.

Apart from any issues relating to the specific proposals themselves, the manner in which these proposals have been presented to the Legislature is worthy of note. Governor Cuomo effectively neutralized many of the key interest groups by inviting them to serve as part of the MRT that was responsible for advancing these proposals and then maintained their support for his budget proposals by including one or more proposals of particular interest to each of them. Taking a page from his predecessors, including Governors Pataki and

Paterson, the Governor has included many of the substantive proposals in both so-called Article VII legislation and in appropriation language. Based on court decisions at the turn of this century that examined the New York State Constitution's budget-making provisions, there are limits on the Legislature's ability to modify the Governor's appropriations and budgetary proposals—and, by incorporating many substantive changes in the appropriation bills, the Governor is seeking to exploit that Executive Branch advantage. As the deadline approached, Governor Cuomo threatened (as Governor Paterson did last year) that, if the deadline was missed, he would submit emergency budget provisions that contained his budget proposals: if the Legislature failed to enact his budget as is, State government would shut down.

In addition, as is further described below, many of the Medicaid-related budget proposals grant unprecedented authority to the Department of Health and the Division of Budget to make Medicaid payment and benefit changes to maintain Medicaid spending within a new global cap and provide substantial flexibility to the Department and other state agencies in the implementation of many of these initiatives.

Overview of Medicaid Redesign Proposals

As noted, the Executive Budget established a $2.85 billion target for reducing Medicaid expenditures (State share) and directed the MRT to meet it. Before the MRT concluded its work, the Budget Division announced that, due to some re-estimates of likely Medicaid spending, the new target for Medicaid reductions should be $475 million less than had been estimated, leaving a $2.3 billion target for reductions. The MRT then adopted a $2.3 billion reduction plan, which has been largely enacted by the Legislature.

The enacted Executive Budget now contains essentially three components: First, a series of more or less traditional across-the-board reductions, including a two percent reduction in Medicaid payments to health care providers and the elimination of trend factors. Second, the MRT advanced a long list of other specific proposals that affect various categories of Medicaid expenditures and that fall into several broad categories:

- Enhanced care coordination for high-cost, complex patients and other health care delivery system reforms, including:
  - requirements that community-based long term care Medicaid recipients enroll in Managed Long Term Care (MLTC) plans or other care coordination programs;
  - the elimination of a series of other limitations on the enrollment of individuals in mainframe managed care programs;
  - the establishment of patient-centered medical homes and health homes to promote coordinated care for various populations;
  - the creation of behavioral health organizations to coordinate care for seriously mentally ill beneficiaries;
  - an Accountable Care Organization Demonstration Program to test the ability of ACOs to assume a role in managing and coordinating care for a designated population.

- Regulatory relief, including medical malpractice liability reforms and streamlined regulatory reporting requirements, designed to reduce the costs of providing care;
- Modest benefit reductions in selected areas; and
- Payment changes for various provider categories that target overutilization by home health agencies and behavioral health providers and that establish new payment methodologies, such as a new episodic payment system for home health agencies, modeled on the Medicare prospective payment system.

Finally, to ensure that the spending reductions are satisfied, the MRT proposed, and these amendments would enact, an overall limit (referred to as a global cap) on growth of Medicaid spending for 2011 and subsequent years.

Space does not permit a description of every element of the Medicaid and health care changes enacted in this Budget. Two elements—the global cap on Medicaid spending and a series of medical malpractice reforms—are detailed below.

Medicaid Global Cap. The budget imposes a global cap on the year-to-year rate of growth of Medicaid spending (State share) exceeding the ten-year rolling average of the medical component of the consumer price index, which is approximately 4% per year. During the next two fiscal years, if actual Medicaid expenditures exceed the annual 4% growth limit, the Commissioner of Health is authorized to develop a Medicaid savings allocation plan to produce further savings to maintain spending within the prescribed cap.

In consultation with stakeholders and the Legislature, the Commissioner is required to make these reductions uniformly among categories of services and geographic regions of the State, to "the extent practicable," but is authorized to apply the reductions on a non-uniform basis if he has sufficient grounds to do so. Non-uniform reductions may be authorized if the Commissioner:

- allocates the reductions on the basis of the specific categories of services that are causing the increase in excess of the 4%;
- seeks to maintain safety net services in underserved regions;
- seeks to secure the benefits of pursuing innovative payment models contemplated by federal health reform; or
- takes steps that are less administratively burdensome to recipients and providers.

While the exercise of this authority by the Commissioner is contingent upon the inability of the other reforms to reach the target and the unsuccessful efforts by providers, health plans, and care management organizations to contain Medicaid expenditures voluntarily, the Commissioner would be given unprecedented authority to reduce Medicaid spending unilaterally, albeit subject to various consultation and notice requirements that have been included in the final budget agreement. The legislation contemplates that those reductions could include:

- modifying or suspending reimbursement methods;
- modifying Medicaid program benefits;
- seeking federal waivers; and
- suspending time frames for notice, approval or certification of rate requirements.

Medical Liability Reform. The MRT proposed and the 30-Day Amendments contain sweeping changes to laws governing medical malpractice and establish a medical indemnity fund to cover claims relating to medical injuries suffered by newborns. The Legislature did not ultimately enact one of the most controversial proposals, which would have placed a $250,000 cap on damages awarded in medical, dental and podiatric malpractice for pain and suffering (non-economic damages). The issue of a cap on non-economic damages has been debated in New York for decades and would, according to actuaries for malpractice carriers, have a dramatic impact on reducing medical malpractice premiums—but was strongly opposed by the trial lawyers and bar associations and was not included in the budget agreement.

The elements that remained included the following:

- ***Medical Indemnity Fund.*** In the case of birth-related neurological injuries, future medical expenses will be paid by a newly created State fund, called the Medical Indemnity Fund. These cases are considered among the most expensive and problematic in the tort litigation system; proof of whether sub-par physician performance actually caused the injury is elusive, yet the lifelong costs (and sympathy of juries and the community) are profound—and the extraordinarily high malpractice insurance costs driven by these cases has limited access to obstetrical services in a growing number of communities. Most aspects of the traditional tort litigation system would continue to apply: plaintiffs would need to prevail in a litigation settlement or court verdict in order to be compensated, in contrast to prior proposals that had included a no-fault system for birth-related neurological injuries, which would have compensated such injuries and eliminated legal contests over whether the injuries were caused by malpractice. Under this proposal, attorneys for plaintiffs would be compensated in the same fashion as in the past (usually a contingency fee as a percentage of the amount awarded).

The law's effective date seeks to make these provisions effective with respect to any lawsuit that has not reached a settlement or verdict, including pending actions. Funding for the new Medical Indemnity Fund would come from a 1.6% assessment on hospitals' obstetric revenue, which is expected to raise $30 million. The fund would pay all medically necessary health care costs of qualified plaintiffs, except for those costs borne by collateral sources, such as health insurance. Payments to providers would be made at the Medicaid rate.

- ***Hospital quality initiatives.*** A patient safety workgroup for obstetrics would be created in the DOH. It would collect and disseminate information regarding best practices, and design new programs to produce better outcomes.
- ***Other malpractice-related reforms.*** Mandatory settlement conferences would occur soon after cases are ready for trial. Proposals to strengthen existing provisions protecting the confidentiality of quality assurance activities undertaken by health care entities and to require more disclosure of expert witnesses were not enacted.

These and other provisions in the 2011-12 budget may constitute some of the most significant changes to the Medicaid program since its inception and may well set the direction of the Cuomo Administration's health policy for the remainder of his term. With the budget behind the Administration, attention has now turned to the remaining longer-term work of the Medicaid Redesign Team and to the necessary steps New York State will have to take to implement federal health reform. Stay tuned.

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

In the New York State Agencies

By Francis J. Serbaroli

Mental Health Services—General Provisions; Community Based Service System for Children; Operation of Outpatient Programs

Notice of adoption. The Office of Mental Health amended Parts 501, 507 and 587 of Title 14 NYCRR to add a definition of "serious emotional disturbance." Filing date: October 2, 2010. Effective date: October 27, 2010. See N.Y. Register October 27, 2010.

Prenatal Care Assistance Program (PCAP)

Notice of proposed rulemaking. In a consensus rulemaking, the Department of Health repealed sections 85.40 and 86-4.36 of Title 10 NYCRR to remove a Prenatal Care Assistance Program (PCAP) provision that is no longer in existence. See N.Y. Register November 10, 2010.

Correction of an Inaccurate State Agency Name

Notice of adoption. The Office of Mental Health amended Part 505 of Title 14 NYCRR to update the name of the Commission on Quality of Care and Advocacy for Persons with Disabilities within the existing regulation. Filing date: October 25, 2010. Effective date: November 11, 2010. See N.Y. Register November 10, 2010.

Correction of an Inaccurate Address in Existing Regulation

Notice of adoption. The Office of Mental Health amended Part 510 of Title 14 NYCRR to correct the address of the Department of State, Committee on Open Government. Filing date: October 25, 2010. Effective date: November 11, 2010. See N.Y. Register November 10, 2010.

Certified Home Health Agency Program

Notice of adoption. The Department of Health amended section 505.23 of Title 18 NYCRR to repeal provisions of the Department's home health services regulations that are

obsolete due to expired statutory authority. Filing date: November 2, 2010. Effective date: November 17, 2010. See N.Y. Register November 17, 2010.

Public Water Systems

Notice of proposed rulemaking. The Department of Health gave notice of its intent to amend Subpart 5-1 of Title 10 NYCRR to incorporate mandatory regulations (federal Ground Water Rule) to increase protection against microbial pathogens in ground water. See N.Y. Register November 17, 2010.

Mt. Sinai-Queens Merged Rates

Notice of emergency rulemaking. The Department of Health amended section 86-1.31 of Title 10 NYCRR to no longer require that a merger, acquisition or consolidation needs to occur on or after the year the rate is based upon. Filing date: December 2, 2010. Effective date: December 2, 2010. See N.Y. Register December 22, 2010.

Hospital Minimum Standards and Appropriateness Review

Notice of adoption. The Department of Health amended sections 405.6, 405.7, 405.19 and 708.5 of Title 10 NYCRR to decrease the look-back period for credentialing from 10 to 5 years and to extend the physician coverage time for EDs from 20 to 30 minutes. Filing date: July 12, 2010. Effective date: December 22, 2010. See N.Y. Register December 22, 2010.

Post-Anesthesia Evaluations at Free-Standing and Hospital Off-Site Ambulatory Surgery Centers (ASCs)

Notice of adoption. The Department of Health amended section 755.6 of Title 10 NYCRR to authorize those individuals who can administer anesthesia in Free-Standing and Hospital Off-Site ASCs to do post anesthesia evaluations. Filing date: December 14, 2010. Effective date: December 29, 2010. See N.Y. Register December 29, 2010.

Standards of Construction for Health Care Facilities

Notice of adoption. The Department of Health amended Parts 711, 712, 713, 714, 715 and 716 of Title 10 NYCRR to update and clarify construction and physical environment standards for hospital, nursing home and certain ambulatory care facilities. Filing date: December 14, 2010. Effective date: December 29, 2010. See N.Y. Register December 29, 2010.

NYS Newborn Screening Panel

Notice of emergency rulemaking. The Department of Health amended section 69-1.2 of Title 10 NYCRR to add Severe Combined Immunodeficiency (SCID) to NYS Newborn Screening Panel. Filing date: December 16, 2010. Effective date: December 16, 2010. See N.Y. Register January 5, 2011.

Audited Financial Statements

Notice of emergency rulemaking. The Insurance Department repealed Part 89; and added Part 89 (Regulation 118) to Title 11 NYCRR to implement provisions of Insurance Law Section 307(b), and add provisions required pursuant to the federal Sarbanes-Oxley Act of 2002. Filing date: December 17, 2010. Effective date: December 17, 2010. See N.Y. Register January 5, 2011.

Potentially Preventable Readmissions

Notice of emergency rulemaking. The Department of Health amended section 86-1.37 of Title 10 NYCRR to implement a revised reimbursement policy related to hospital readmissions that are determined to be potentially preventable. Filing date: December 28, 2010. Effective date:

December 28, 2010. See N.Y. Register January 12, 2011.

Cost of Examinations—Medicaid

Notice of proposed rulemaking. The Department of Health gave notice of its intent, through a consensus rulemaking, to amend section 360-5.5 of Title 18 NYCRR to change citation referenced within existing regulation. See N.Y. Register January 12, 2011.

Financial Statement Filings and Accounting Practices and Procedures

Notice of proposed rulemaking. The Insurance Department gave notice of its intent to amend Part 83 (Regulation 172) of Title 11 NYCRR to update the regulation to conform to NAIC guidelines, statutory amendments, and to clarify existing provisions. See N.Y. Register January 12, 2011.

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

Notice of proposed rulemaking. The Insurance Department gave notice of its intent to amend Part 52 of Title 11 NYCRR to establish standards for an internal appeal procedure for longterm care insurance. See N.Y. Register January 12, 2011.

Distributions from the Health Care Initiatives Pool for Poison Control Center Operations

Notice of emergency rulemaking. The Department of Health amended section 68.6 of Title 10 NYCRR to revise the methodology for distributing HCRA grant funding to Regional Poison Control Centers (RPCCs). Filing date: December 31, 2010. Effective date: January 1, 2011. See N.Y. Register January 19, 2011.

Hospital Inpatient Reimbursement

Notice of emergency rulemaking. The Department of Health amended Subpart 86-1 of Title 10 NYCRR to modify current reimbursement for hospital inpatient services due to the implementation of APR DRGs and rebasing of hospital inpatient rates. Filing date: January 18, 2011. Effective date: January 18, 2011. See N.Y. Register February 2, 2011.

Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content

Notice of emergency rulemaking. The Department of Health amended Part 59 of Title 10 NYCRR to update technical standards for blood and breath alcohol testing conducted by law enforcement. Filing date: January 18, 2011. Effective date: January 18, 2011. See N.Y. Register February 2, 2011.

Standards Pertaining to Payment for Hospitals Licensed by the Office of Mental Health

Notice of adoption. The Insurance Department amended Part 574 of Title 14 NYCRR to make minor technical corrections to existing regulation and use "person-first" language. Filing date: January 13, 2011. Effective date: February 2, 2011. See N.Y. Register February 2, 2011.

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

Notice of adoption. The Office of Mental Health amended Part 578 of Title 14 NYCRR to carve out the cost of eligible pharmaceuticals from the per diem reimbursement rate for Residential Treatment Facilities. Filing date: January 12, 2011. Effective date: February 2, 2011. See N.Y. Register February 2, 2011.

Ambulatory Patient Groups (APGs) Payment Methodology

Notice of adoption. The Department of Health amended Subpart 86-8 of Title 10 NYCRR to refine the APG payment methodology implemented on December 1, 2008, which gives reimbursements for certain ambulatory care fee for service medical services. Filing date: December 21, 2010. Effective date: January 5, 2011. See N.Y. Register January 5, 2011.

Notice of emergency rulemaking. The Department of Health amended Subpart 86-8 of Title 10 NYCRR to refine the APG payment methodology to update the APG weights at least once a year as required by regulation. Filing date: December 31, 2010. Effective date: January 1, 2011. See N.Y. Register January 19, 2011.

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

New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

- ***Episcopal Residential Health Care Facility, Inc.*** (DOH administrative hearing decision dated November 12, 2010, John Harris Terepka, Administrative Law Judge). In a decision on submissions without a hearing, the Administrative Law Judge sustained an audit adjustment to the facility's mortgage interest expense reimbursement for 2005 based on receipt by the facility in the 2003 base year of a return of a portion of its mortgage debt reserve funds. The mortgage had been sold by the Dormitory Authority to a private entity.
- ***West Midtown Medical Group, Inc.*** (DOH administrative hearing decision dated November 19, 2010, James F. Horan, Administrative Law Judge). In this case, the ALJ sustained the OMIG determination that the provider failed to file a timely notice of appeal from the final audit report. 18 NYCRR § 519.7 requires that a request for a hearing be filed within sixty days from receipt of the final audit report. The right to an administrative hearing was therefore waived.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

- ***Owners of Pharmacy Arrested for Allegedly Operating Queens Pharmacy Without a Licensed Pharmacist and Dispensing Medications That Were Not Purchased.*** A joint OMIG and

MFCU investigation led to the arrest of the husband and wife owners of an Ozone Park pharmacy. The investigation found that the pharmacy billed Medicaid during the period of time when the supervising pharmacist was on extended sick leave. Neither of the owners were licensed pharmacists. MFCU also conducted an inventory audit covering a four year period which led to charges that the pharmacy billed Medicaid $846,000 more than the amount of drugs it purchased from licensed wholesalers. The individuals were charged with a class D and two class E felonies.

New York State Office of the Medicaid Inspector General Update

Compiled by Marie A. Butchello and Charles Z. Feldman

- OMIG 2010-2011 Work Plan—available on OMIG website.
- Electronic Health Records (EHR) Incentive Program—links and information specific to eligible providers, registration and incentive payments under the program available on OMIG website.
- Provider Compliance Assessment Tool—allows providers to evaluate their compliance programs—available on OMIG website. The tool consists of a ten page questionnaire that seeks information regarding the structure and implementation of a provider's compliance program. Providers are questioned about each of the eight elements required by statute and the corresponding regulations and other compliance requirements. The related Compliance Alert makes clear that the self assessment tool does not ascertain the effectiveness of a provider's compliance program, rather it confirms if the provider has established the framework for an effective compliance program. Providers are urged to use the tool to determine in what areas their plans may be lacking, and are encouraged to share the results with their senior management.
- OMIG has commenced issuing periodic Compliance Alerts. To date, three alerts have been issued and are available for review on OMIG's website: 1) 2010-02: Effectiveness of Medicaid Provider's Compliance Program; 2) 2010-03: Self-Disclosures; 3) 2011-01: Annual Certification 2010.
- OMIG Compliance Webinar #5: Evaluating Effectiveness of Compliance Programs—November 17, 2010—Still Available on OMIG website.
- Joint Release—Manhattan District Attorney Vance Announces Indictment of Manhattan Pharmacist on Charges that He Fraudulently Billed Medicaid More Than $1.8 Million for Prescription Drugs That Were Never Dispensed for the Period April 2009 Through March 2010—November 4, 2010.

- OMIG Compliance Webinar #4: Provider and Third-Party Payer Obligations: Medicaid Third-Party Billing, Payment and Enforcement – October 20, 2010—Still Available on OMIG Website—covered the responsibilities of health care providers under the third-party liability laws and the effect of Section 6402 of the Patient Protection and Affordable Care Act (PPACA) on providers' and payers' third-party responsibilities.
- OMIG Compliance Webinar #3: Self-Disclosure by Medicaid Providers—September 14, 2010—Still Available on OMIG Website – covered self-disclosure guidance issued to providers in March 2009, as well as mandatory disclosure requirements under the Patient Protection and Affordable Care Act (PPACA) and implications for providers who fail to disclose identified overpayments.
- 2009 Annual Report

Corporate Integrity Agreements with the New York State Office of the Medicaid Inspector General

- ***Young Adult Institute, Inc. ("YAI"—1/14/11 – Office for People with Developmental Disabilities).*** YAI entered into a Corporate Integrity Agreement to settle allegations of Medicaid fraud. The allegations centered around YAI's bookkeeping practices that allegedly improperly shifted expenses and losses in order to support requests for appeals and price adjustments to Medicaid. OMIG alleges that YAI improperly submitted these false and/or inaccurate fiscal reports to Medicaid. To settle investigations brought by OMIG, MFCU, and the DOJ, YAI agreed to comprehensive compliance requirements. In addition to certifying that it would adopt a plan that fulfills the statutory requirements of New York State Law, YAI agreed to retain an independent review organization (IRO) to ensure that YAI has an effective and sustainable compliance program. The IRO will audit the effectiveness of YAI's compliance plan, and will present an annual report directly to OMIG. YAI also agreed to adopt comprehensive corporate integrity obligations and agreed to certify that its fiscal reports and annual reports are produced in adherence with certain compliance procedures and regulatory requirements.

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Compiled by Melissa Ann Dizon and Nicholas A. Battaglia

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Melissa Ann Dizon is a third-year law student at Albany Law School. Nicholas Battaglia is a second-year student at Albany Law School. Both are members of the law school's Health Law Society.

For Your Information

By Claudia Torrey

On January 10, 2011, the final rule to implement Title II of the Genetic Information Nondiscrimination Act of 2008 ("GINA") became effective.[1] Title II of GINA protects job applicants, current and former employees, labor union members, apprentices, and trainees from discrimination based on their genetic information; enforcement and governance of GINA is under the federal Equal Employment Opportunity Commission.[2]

Several items are of particular interest in GINA—Title II:

1. **Safe Harbor Language (29 CFR 1635.8(b)(1)(i)(B)):** The final rule provides language employers can use in medical inquiry forms, such as "pre and post" offer medical exams and "fitness-for-duty" exams. By using the safe harbor language, employers avoid liability under GINA if they receive protected genetic information in response to the above mentioned inquiries within the context of an otherwise lawful request for medical information.
2. **Wellness Programs (29 CFR 1635.8(b)(2)):** Employers may not offer a financial inducement to employees for genetic information in connection with voluntary wellness programs and the health (risk) assessments attached to such programs. Financial offers in these situations can be extended regarding questions about family medical history or other genetic information if (a): the assessment specifically identifies which questions request genetic information; and (b): clear language is utilized that would reasonably likely be understood by those completing the assessment that the questions are optional, and the financial reward will be provided to employees whether or not they complete that portion of the health assessment.
3. **Social Media Situations (29 CFR 1635.8(b)(4)):** In a nutshell, if employers obtain protected genetic information "inadvertently" they have not violated GINA (ex.: a Google search just by using the employee's name; information from a Facebook or LinkedIn page via valid permission, etc.); however; performing an intentional search that is likely to yield genetic information is not permissible!

While the final rule does not deviate greatly from the proposed regulations, it contains information that your employer clients need to know.

Endnotes

1. 29 CFR Part 1635 (2011); see also Vol. 75, No.216 Federal Register 68912-68939 (November 9, 2010).
2. Infra.; Title I of GINA concerns health plans sponsored by private employers, unions, and insurance issuers of Medigap, group, and/or individual health insurance.

Claudia Torrey, Esq. is a Charter Member of the Health Law Section and a Sustaining Member of the New York State Bar Association.

Implementing the Family Health Care Decisions Act: Introduction to the Special Edition

By Richard N. Gottfried

The enactment of the Family Health Care Decisions Act was an historic, long-overdue, and important step forward for health law in New York. The long legislative process was tortuous—and torturous. However, New Yorkers can be proud of many aspects of that process.

First, the bill was the work product of an extraordinary New York institution, the Task Force on Life and the Law, created in 1985 by then-Governor Mario Cuomo. Made up of diverse and thoughtful leaders with a superb staff, the Task Force has wrestled with a variety of complex difficult issues and produced a series of scholarly reports and well-drafted legislative proposals, most of which have been enacted into law.

Second, the legislative struggle was at all times a dispute grounded in firm beliefs about moral issues and the best interests of New York patients. This was not a fight about special interests trying to feather their nests. Ultimately, the bill prevailed because an extraordinarily broad coalition of health care providers, patient advocates, religious groups, and legal organizations—particularly the New York State Bar Association—never relented. Several individuals—especially Tracy Miller, Barbara Shack, Carl Coleman and Robert Swidler—worked in the finest traditions of individuals in a democracy.

You read that everything in Albany is run by "three men in a room." I can assure you that if my workplace bore any resemblance to that caricature, I would have left many years ago to do something else. One demonstration of the untruth of that caricature is the effort to enact the FHCDA. If "three men in a room" in fact ran Albany, the bill would have become law a long time ago.

The work on this issue continues.

We are working to amend the law to cover health care decisions outside hospitals and nursing homes, starting with decisions about hospice care. Ultimately, it should be amended to apply to all health care decisions in all settings. The law is complicated because it deals with a variety of circumstances and reflects thoughtful hard-fought compromises. As a result, expanding it beyond hospital and nursing home settings is complicated.

The next step is to review the situation relating to patients with mental illness and with developmental disabilities. Currently, they are covered by a separate statute enacted in 2002. I believe there is a strong case for bringing them within the FHCDA. The FHCDA includes a provision directing the Task Force on Life and the Law to study this issue, in consultation with representatives of the affected community, and develop recommendations.

It is important that legal practitioners in the field, as well as health care providers and family members, let us in the Legislature know how the law is working and what changes are needed. It was people in the field who helped get the FHCDA drafted and enacted. Their continued involvement will be essential to making sure it works well.

This issue of the *Health Law Journal* will help people understand the new law and help advance the effort to improve it.

Richard N. Gottfried is the Chair of the New York State Assembly Committee on Health.

Frequently Asked Questions About the Family Health Care Decisions Act[1]

Editorial Board, New York State Bar Association Family Health Care Decisions Act Information Center

Introduction

This FAQ Section was prepared by, and will be maintained by, the FHCDA Information Center Editorial Board. The Editorial Board Members are:

- **Kathy Faber-Langendoen, MD**, Medical Alumni Endowed Professor of Bioethics and Professor of Medicine SUNY Upstate Medical University, Syracuse, NY
- **Jack P. Freer, MD**, Professor of Medicine, University at Buffalo and Kaleida Health, Medical Director, Ethics, Buffalo, NY
- **Hon. Richard N. Gottfried**, Chair, NYS Assembly Health Committee
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- **Salvatore J. Russo, Esq**., General Counsel, NYC Health and Hospitals Corporation, NYC
- **Robert N. Swidler, Esq.**, General Counsel, Northeast Health, Troy NY (FAQ Page Editor)

Editorial Board members were jointly appointed by the Chair of the NYS Bar Association Health Law Section and Editor of the NYS Bar Association ***Health Law Journal***. Every entry has been reviewed and approved by at least three Editorial Board Members (in addition to the author of the entry).

Readers can propose FAQs or answers or both, or critique answers, through the FHCDA Listserve. See www.nysba.org/fhcda.

FAQ answers reflect the personal viewpoints of the Editorial Board members who approved those items. They are not the official position of NYSBA, or any governmental entity, or the organizations that the Editorial Board members are affiliated with. FAQ answers are offered for the independent and critical consideration by the reader, and should not be regarded as legal advice.

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I. Definitions (PHL § 2994-a)

Q 1. ***Adult—The FHCDA defines "Adult" to mean "any person who is eighteen years of age or older or has married," but the Health Care Proxy Law and other laws also regard a person as an adult if the person is the parent of a child. Why is the FHCDA definition of adult different?***

A The Task Force that developed the FHCDA proposal reasoned that just because a minor-—perhaps even a 13- or 14-year-old—is the mother or father of a child, does not mean that the minor has the capacity or maturity to decide on their own about whether to forgo life-sustaining treatment. Accordingly, the FHCDA does not treat a minor parent as an "adult," but rather as an "emancipated minor." As such, the minor can consent to treatment on par with an adult, but a decision to forgo life-sustaining treatment would require approval of an Ethics Review Committee.

Q 2. ***Attending physician—Can a resident be an "attending physician" for purposes of the FHCDA?***

A Neither the Department of Health nor the State Education Department has addressed this. But it seems likely that a resident practicing under a limited permit (Ed. Law § 6526) can act as an attending physician for FHCDA purposes. It seems less likely that a resident or intern practicing under a licensing exemption (Ed. Law § 6528) can act as an attending physician for FHCDA purposes.

Q 3. ***Close friend—How does the FHCDA definition differ from the definition in the former DNR Law?***

A The FHCDA simply requires the close friend to sign a statement; the former DNR Law required the close friend to sign an affidavit (i.e., a statement sworn before a notary). Also, the FHCDA makes it clear that the term could include a relative who is not close enough to be on the surrogate list.

Q 4. ***Domestic partner—Where did the definition of "domestic partner" come from?***

A It is substantially similar to the definition that is in PHL 4201, which gives the domestic partner of a deceased person the right to make decisions regarding disposition of the deceased person's remains.

Q 5. ***Health care—The definition says that "Providing nutrition or hydration orally, without reliance on medical treatment, is not health care under this article and is not subject to this article." What does "Providing nutrition or hydration orally, without reliance on medical treatment" refer to, and what is the purpose of the phrase?***

A The phrase "providing nutrition or hydration orally, without reliance on medical treatment" simply refers to feeding a patient, i.e., giving the patient food or drink to swallow. So the FHCDA applies to surrogate decisions regarding the provision of nutrition and hydration by tubes placed in the patient's nose, stomach, intestines or arms; but it does not apply to decisions regarding giving a patient food or drink to swallow.

Q 6. ***Health or social service practitioner—This definition includes certain licensed health care professionals (i.e., a registered professional nurse, nurse practitioner, physician, physician assistant, psychologist or licensed clinical social worker) but only if the professional is "acting within his or her scope of practice." A later section says that such professionals can provide the required concurring determination regarding a patient's decisional capacity. Is that determination within the scope of practice of such professionals?***

A The State Education Department Office of Professions, in an informal response to this question from the Department of Health, indicated any registered professional nurse, nurse practitioner, psychologist or licensed clinical social worker can concur (or not concur) with an attending physician's capacity determination within their scope of practice. DOH has not yet issued a statement regarding the scope of practice for physician assistants. Note that hospitals and nursing homes must adopt written policies identifying the training and credentials of health or social services practitioners qualified to provide concurring determinations in their facilities. Also, just because something is within the scope of practice, the practitioner is not necessarily competent to do it.

Q 7. ***Life-sustaining treatment—Why does the FHCDA definition of life-sustaining treatment include the statement that "For the purpose of this article, cardiopulmonary resuscitation is presumed to be life-sustaining treatment without the necessity of a determination by an attending physician"?***

A The FHCDA allows a surrogate to make decisions about the withholding or withdrawal of life-sustaining treatment. The statement about resuscitation makes it clear that such authority includes the authority to make decisions about the withholding or withdrawal of resuscitation—that is, to consent to a do-not-resuscitate order.

II. Applicability; Priority of Certain Other Surrogate Decision-Making Laws and Regulations (PHL § 2994-b)

Q 1. ***Why does the FHCDA apply only in hospitals and nursing homes?***

A The Legislature wanted to introduce this law in institutional settings where there would be greater oversight and safeguards. However, it recognized that there is a need to authorize surrogate decision making in other settings as well (e.g., PHL Article 40 hospice, ambulatory surgery centers, clinics, doctor and dentist offices, home care, etc.). It therefore directed the Task Force on Life and the Law to study extending the FHCDA to other settings and to make recommendations. See NY Laws of 2010, Ch. 8 Section 28.1.

Q 2. ***Would the FHCDA apply in an off-campus clinic operated by a hospital?***

A Yes. An "extension clinic" is considered part of the general hospital.

Q 3. ***What is a court-appointed guardian under Surrogate's Court Procedure Act (SCPA) Article 17-A and why does the FHCDA not apply to persons who have such guardian?***

A SCPA Article 17-A creates a process for the court appointment of a guardian for an adult with mental retardation or with developmental disabilities that cause similar intellectual impairments. Such guardian has the authority to make health care decisions, including decisions about life-sustaining treatment, under rules and principles set forth in that article. There was considerable debate about whether the FHCDA should replace SCPA 17-A decision-making rules and principles, and directing the guardian to follow the FHCDA rules. The Legislature decided to let SCPA Article 17-A rules and principles continue to apply for now, but it directed the Task Force on Life and the Law to form a subcommittee to study the matter further.

Q 4. ***What is SCPA § 1750-b, and why does the FHCDA not apply to persons described in that section for decisions to withdrawal life-sustaining treatment?***

A SCPA § 1750-b is a section in SCPA Article 17-A that allows a family member, close friend, or surrogate decision-making panel, without being appointed as guardian by the court, to make a decision about life-sustaining treatment for a person with mental retardation or a similar developmental disability who meets certain clinical criteria.

While there was debate whether SCPA § 1750-b or the FHCDA should apply to such decisions, the Legislature decided to let SCPA Article § 1750-b continue to apply. However, it directed the Task Force on Life and the Law to form a subcommittee to recommend whether the FHCDA rather than SCPA § 1750-b should apply to such persons.

Q 5. ***The FHDCA says that it does not apply when consent to treatment is governed by "the mental hygiene law or regulations of the office of mental health or the office of mental retardation and developmental disabilities OMRDD or OMH regulations" What are those laws and regulations, and when would they ever apply to a hospital or nursing home patient?***

A First, OMRDD recently changed its name to the Office for Persons with Developmental Disabilities. OPWDD regulations (14 NYCRR § 633.11) govern surrogate consent to treatment for residents of OPWDD-operated and licensed facilities. Such regulations would continue to be applicable to a person who was removed to a general hospital or nursing home for treatment, but not discharged from such OPWDD-operated or licensed facility.

OMH regulations (14 NYCRR § 27.9 and § 527.8) govern surrogate consent to treatment and objection to treatment for patients of OMH-operated and licensed psychiatric hospitals and hospital units. Such regulations would continue to be applicable to person who was removed to a general hospital or nursing home for treatment, but not discharged from such OMH operated or licensed psychiatric hospital or unit.

In contrast, with respect to a person who was admitted to a hospital or nursing home from an OMH-licensed community residence, consent or objection to treatment would be based on the same principles that would apply to any other hospital patient. So if the patient lacked decision-making capacity and did not have a health care agent, the FHCDA would govern decisions for the patient.

Q 6. ***What role does a Mental Hygiene Law Article 80 Surrogate Decision Making Committee (SDMC) have now that the FHCDA authorizes surrogate decision making for hospital and nursing home patients?***

A MHL Article 80 and 14 NYCRR Part 710 authorize a local SDMC to make treatment decisions for persons with mental disabilities who reside or once resided in an OPWDD, OMH or OASAS facility, or who receive or once received certain OPWDD services, and do not have a family member to make such decisions.

SPCA § 1750-b makes the SDMC the decision-maker of last resort for persons with mental retardation and certain other developmental disabilities for purposes of

life-sustaining treatment decisions. As a result, the SDMC is the surrogate of last resort for decisions to withdraw or withhold life-sustaining treatment for hospital or nursing home patients with mental retardation and certain other development disabilities.

OPWDD surrogate decision-making regulations make the SDMC the surrogate of last resort for residents of OPWDD facilities. As a result, the SDMC is also the surrogate of last resort for decisions to consent to treatment for those hospital or nursing home patients for whom OPWDD surrogate decision-making regulations apply.

In addition, SDMC is available, but optional, to provide consent to treatment for decisions in a hospital or nursing home for an eligible person when OPWDD regulations and SCPA § 1750-b do not apply.

Finally, the SDMC continues to have the same role that it currently has for treatments provided outside of a hospital or nursing home, for eligible persons.

Under 14 NYCRR Part 710, a SDMC for a person with mental illness can refuse major medical treatment. In some cases, this would be withholding life-sustaining treatment.

Q 7. ***It is very difficult to identify which surrogate decision-making law applies to hospital or nursing home patients who have developmental disabilities or mental illness. Is there a chart that summarizes this, perhaps with examples?***

A Yes. See the document "Surrogate Decision Making for Patients With Mental Disabilities: A Chart of Applicable Laws and Regulations," which is linked to the FHCDA Information Center website.

III. Determination of Incapacity (§ 2994-c)

Q 1. ***Why does this section require the attending physician to "confirm the adult patient's continued lack of decision-making capacity before complying with health care decisions made pursuant to this article, other than those decisions made at or about the time of the initial determination"; what does "confirm" mean, and what does "at or about the time of the initial determination" mean?***

A A patient's ability to make decisions may fluctuate from day to day, and a patient may be capable of making some decisions and not others. Accordingly the FHCDA requires the physician to "confirm" the continued lack of capacity, if a surrogate continues to make decisions on the patient's behalf.

The FHCDA does not impose any standards with respect to confirming incapacity or specify how the determination should be made. Presumably, the determination will require reasonable steps under the circumstances: for a patient who has been in a coma, or who has advanced dementia, it may be as simple as a notation, "incapacity confirmed." For a patient whose capacity has been more fluid, the physician should rely upon his or her judgment about the steps needed to confirm incapacity, and document the basis for the confirmation in the medical record.

"At or about the time" is a necessarily imprecise term, and allows the attending physician to exercise judgment about whether the last determination of incapacity was recent enough to be reliable.

Q 2. ***While the FHCDA allows a concurring determination of incapacity to be made by a health or social services practitioner, the Health Care Proxy Law seems to still requires that a physician provide the concurring determination. Is that correct, and is there a reason for it?***

A That is correct, and while there might be some rationale for the difference (e.g., the FHCDA has other safeguards that the proxy law does not) it seems that this is an instance where the proxy law should be amended to "catch up" with the FHCDA standard for concurring determinations.

Q 3. ***Can the physicians make a determination of capacity, without personally examining the patient, e.g., over the phone?***

A Unlike the prior DNR Law, the FHCDA no longer contains a "personal examination" requirement. As a result the physician only needs to comply with the applicable professional standard of care. In most instances, that would require a personal examination, but in limited circumstances it might not, such as when the patient lacks capacity as a result of being unconscious.

IV. Health Care Decisions for Adult Patients by Surrogates (§ 2994-d)

A. Identifying the Surrogate

Q 1. ***Is the "surrogate" a court appointed position?***

A No. It is a person in the highest category on the surrogate list who is available, willing and competent to make decisions for the incapable patient, and is identified when there is no health care agent.

Q 2. ***The highest priority is "A guardian authorized to decide about health care" pursuant to MHL Article 81. Does that include a guardian appointed prior to the date the FHCDA became effective?***

A The FHCDA is not explicit about this, but the answer in all likelihood is yes.

Q **3.** ***When the highest category is an adult son or daughter, and there is more than one such person, are they all surrogates? If not, then who chooses the surrogate, and on what basis?***

A The FHCDA states that "one person" from the list is the surrogate. While the FHCDA does not specify who identifies the surrogate when more than one person is in the highest category, it necessarily will be the responsibility of the hospital or nursing home to identify the surrogate. In most cases, this should be resolved without difficulty—usually the adult sons and daughters can agree upon the surrogate. In other cases it will be apparent to the hospital staff that one of the patient's adult children is best able to speak of the patient's previous wishes and, if the patient's wishes are not known, the patient's best interests. If there is a dispute, efforts should be made to resolve it informally if possible (e.g., through team meetings, ethics consultation or mediation or the hospital ethics process) or else the matter should be referred to the Ethics Review Committee.

Q **4.** ***What if someone lower down on the surrogate list objects to the decision of the surrogate? How would the hospital respond? For example, would the hospital withdraw treatment from a patient despite objections by the adult child because a domestic partner is higher in priority than the adult child?***

A The hospital should first try to resolve the dispute informally. If it cannot be resolved informally, the hospital should refer the matter to the Ethics Review Committee. If the higher priority person insists upon the provision of life-sustaining treatment, the hospital cannot discontinue such treatment without a court order. In such proceeding, the court will consider whether the surrogate is meeting his or her obligation to make health care decisions in accordance with the patient's wishes, including the patient's religious and moral beliefs; or if the patient's wishes are not reasonably known and cannot with reasonable diligence be ascertained, in accordance with the patient's best interests.

If the surrogate directs the withdrawal or withholding of treatment but a lower priority person insists upon the provision of treatment, the hospital generally should seek judicial review before withdrawing or withholding treatment, although it does not have a legal obligation to do so. If the hospital decides to withdraw the treatment in such circumstance, the hospital should notify the objecting person so that such person could seek judicial review if he or she were inclined to do so. In such proceeding, the court will consider the same issue described above: whether the surrogate met his or her obligation to make a decision based on the patient's wishes if known, or else best interests.

Q **5.** ***Would the following persons be considered a brother or sister for purposes of the FHCDA surrogate list: A half-brother or half-sister? A step-brother or step-sister? A brother or sister by adoption? Would a full brother or sister have priority over a half-brother or half-sister?***

A A half-brother or half-sister would be considered a brother or sister. A step-brother or step-sister would not be considered a brother or sister. A brother or sister by adoption would be considered a brother or sister.

Q **6.** ***Would the following persons be considered a son or daughter: A step-son or daughter? An adopted son or daughter?***

A A step-son or step-daughter would not be considered a son or daughter, unless the step-son or step-daughter were adopted. An adopted son or daughter would be considered a son or daughter.

Q **7.** ***What is the role of the designated representative (NYCRR 415.10) in a nursing home? Is the designated representative and surrogate one and the same?***

A The designated representative is a person (or persons) designated in accordance with 10 NYCRR 415.2(f) to exercise certain rights on behalf of a nursing home resident who lacks capacity. A person does not have authority to make health care decisions for a resident by virtue of being a designated representative. A surrogate is the person identified in accordance with the FHCDA to make health care decisions for a resident who lacks capacity. The designated representative and the surrogate will in many cases be the same individual, but they are not necessarily the same individual.

B. Authority of Surrogate

Q **1.** ***Can the surrogate consent on behalf of a patient to an HIV test under PHL § 2781 be obtained under FHCDA***?

A Yes.

Q **2.** ***Can a surrogate consent to experimental treatment?***

A Yes, although if the treatment is part of a study, and therefore constitutes human subject research, other considerations apply (see below).

Q **3.** ***Can the surrogate consent to enrolling the patient in federally regulated human subject research?***

A Federal human subject research regulations allow consent for incapable patients to be enrolled in research protocols to be given by a "Legally Authorized Representative. " That term is defined in 45 CFR § 46.102 to include a person "authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Thus the FHCDA would appear to give the surrogate such authority in many cases, although the scope of that authority is uncertain.

Q **4.** ***Is the surrogate the "personal representative" of the patient under 45 CFR § 164.502(g)(1) ("HIPAA")?***

A Yes, just as a health care agent under a health care proxy is. If the patient lacks capacity, and the surrogate is empowered to make health care decisions, then the surrogate is the "personal representative" under HIPAA.

Q **5.** ***Is the surrogate a "qualified person" under PHL § 18?***

A No, not necessarily. But the surrogate has a right and duty to be informed about the patient's medical condition, prognosis, diagnosis and the alternatives to the proposed treatment as specified under FHCDA (PHL § 2994-d(3)(c)).

Q **6.** ***Does a surrogate's decision remain valid even after the patient is discharged from the hospital or nursing home?***

A The FHCDA states that it applies only to decisions regarding health care "provided in a hospital." PHL 2994-b.1. (The term "hospital" is defined to include nursing homes as well). But it would be reasonable to read the FHCDA as governing decisions regarding care that is initially provided in the hospital, but continues after discharge pursuant to the same consent. Thus a surrogate could consent on behalf a hospital patient to a course of chemotherapy that begins during hospitalization. Or a surrogate could consent on behalf of a hospital patient to elect hospice, with such hospice services continuing after discharge.

Also, medical orders issued on the DOH-5003 or DOH-3474 forms do not have to be re-issued in hospice, but if the hospital or nursing home uses another form, medical orders to withhold life-sustaining treatment must be re-issued in hospice.

Q **7.** ***Can a surrogate consent to the patient's discharge from a hospital, and admission to a post-acute care facility or program?***

A The FHCDA authorizes only surrogate decisions regarding health care "provided in a hospital" or nursing home. That would clearly include the decisions regarding admission to and discharge from a hospital or nursing home. But the FHCDA would appear not to govern decisions to admit a patient into other post-acute facilities or programs such as home care or assisted living. Even so, such facilities and programs should be no less willing to accept admission and financial decisions by family members than they were before the FHCDA was enacted.

Q **8.** ***Can a surrogate direct the discharge of a patient against medical advice?***

A The surrogate can make any decision that the patient, if capable, could have made, which could include leaving against medical advice. However, the surrogate is obligated to make decisions based on the patient's wishes if known, or else the patient's best interests. So a provider could seek to block a surrogate's decision to remove a patient if the decision was inconsistent with that standard. Moreover, if the discharge involved the withdrawal or withholding of life-sustaining treatment, the provider could also oppose the discharge if the decision did not meet the criteria for the withdrawal or withholding of treatment.

Q **9.** ***Can a surrogate consent to donation of a patient's organ's after death?***

A No, not by virtue of being surrogate. Consent to organ donation is governed by the state's Uniform Anatomical Gift Act, not the FHCDA. But the UAGA has a decision-maker list similar to that in the FHCDA.

Q **10.** ***Does the FHCDA give the surrogate access to the patient's medical record?***

A Yes. The FHCDA gives the surrogate "the right to receive medical information and medical records necessary to make informed decisions about the patient's health care." Like a health care agent, the surrogate has this right only after it has been determined that the patient lacks capacity and the surrogate's authority to make health care decisions has commenced.

Q **11.** ***Can a surrogate apply for Medicaid on behalf of an incapable patient?***

A Yes. Federal Medicaid regulations allow a written application from "the applicant, an authorized representative, or, if the applicant is incompetent or incapacitated, someone acting responsibly for the

applicant." 42 CFR § 435.907(a). This would seem to include a FHCDA surrogate.

C. Prior Decision of Adult Patient

Q 1. ***What is the purpose of the "prior decision" clause—the provision that states as follows?***

> *(ii) Nothing in this article shall obligate health care providers to seek the consent of a surrogate if an adult patient has already made a decision about the proposed health care, expressed orally or in writing or, with respect to a decision to withdraw or withhold life-sustaining treatment expressed either orally during hospitalization in the presence of two witnesses eighteen years of age or older, at least one of whom is a health or social services practitioner affiliated with the hospital, or in writing.*

A The FHCDA was not intended to impose surrogate-decision making upon patients who, prior to losing capacity, made their own decision about treatment. Accordingly, the FHCDA provides that there is no need to seek a surrogate decision if the patient made a prior oral or written decision consenting to a treatment.

However, there were concerns about an attending physician withdrawing or withholding life-sustaining treatment without a surrogate decision based only upon information that the patient had at one time verbally stated a wish to forgo such treatment. Accordingly, the FHCDA provides that there is no need to seek a surrogate decision regarding the withdrawal or withholding of life-sustaining treatment only if the patient's prior decision to forgo life-sustaining treatment was made either (i) orally, during hospitalization, and witnessed by two persons, including one health or social services care practitioner, or (ii) in writing.

In cases that do not meet this requirement—i.e., where the patient's oral statements were made prior to hospitalization or nursing home admission or without witnesses—a surrogate would make the decision. But the surrogate would still be bound to make a decision in accord with what the patient would have chosen.

Note that when a patient arrives at the hospital with a nonhospital DNR order, or a DNR order from another facility, special rules apply. See Q&A #3 below.

Q 2. ***What sort of writings and oral statements would suffice, and what sort would not?***

A A patient's prior written or oral consent to the provision of treatment should be adequate to rely upon without seeking a surrogate decision if it reasonably evidences that consent. However, a prior oral or written decision to withdraw or withhold life-sustaining treatment should be sufficiently specific to have met the "clear and convincing evidence" standard before it may be relied upon without seeking a surrogate decision, inasmuch as the clause was not intended to change pre-FHCDA reliability standards for prior decisions by the patient himself or herself. This means that the decision must clearly apply to both the life-sustaining treatment under consideration and the medical circumstances, e.g., terminal illness.

Q 3. ***If a patient is admitted to a hospital with a nonhospital DNR order (including a MOLST form), or with a DNR order that was entered at another facility, can that be honored even if the patient had consented to it prior to the current hospitalization?***

A Yes. The provisions governing nonhospital DNR orders and inter-institutional transfers obligate the hospital to honor such orders. Hospital emergency services personnel may disregard a nonhospital order not to resuscitate if they believe in good faith that consent to the order has been revoked, or that the order has been cancelled; or if family members or others on the scene (other than such personnel) object to the order and physical confrontation appears likely; and hospital emergency services physicians may direct that the nonhospital order not to resuscitate be disregarded if other significant and exceptional medical circumstances warrant disregarding the order. If the patient is admitted, the medical orders to withhold life-sustaining treatment remain effective until an attending physician examines the patient, whereupon the attending physician must continue the orders, unless the physician determines that the order is no longer appropriate or authorized.

Q 4. ***The FHCDA makes little mention of advance directives. What is the role of a patient's advance directives in this law?***

A As discussed above, a living will, less formal documents and/or oral statements by a patient could provide the basis for the withdrawal or withholding of life-sustaining treatment under the Prior Decision clause, provided it addresses the treatment decision at issue. In addition, while such advance directives might not qualify as a prior decision, they could still provide sufficient evidence of a patient's wishes for a surrogate (or on the case of a patient without a surrogate for the hospital or nursing home) to act based on the patient's known wishes. A health care proxy would still empower a health care agent to make decisions for the patient under the

Health Care Proxy Law, and enable the patient to choose the person who will decide about treatment.

Q ***5. If a now-incapable patient who has lost capacity left an advance directive, or had made a prior oral statement, that clearly established the patient's desire to not have a certain treatment, can a surrogate still require that the treatment be continued?***

A The short, general answer is that the hospital and attending physician are obligated to honor this patient's clear wishes, although they may opt to seek judicial review before implementing the decision. But this is a sensitive question, and different facts may require different guidance.

The FHCDA provides that when a surrogate directs the provision of life-sustaining treatment, a hospital or physician that "does not wish to provide treatment" must nonetheless comply with the surrogate's decision pending either transfer of the patient to a willing hospital or individual health care provider, or judicial review. PHL § 2994-f.3. But such clause would not seem to be applicable to this case, for at least three reasons: First, the plain language of the clause relates to cases where it is the hospital or physician that does not wish to provide treatment; it should not be read to apply to cases where it is the patient who does not want the treatment. Second, when there is a clear prior decision by the patient, there is no need to designate a "surrogate," and thus there is no surrogate to invoke 2994-f.3. Third, applying the clause to this case might violate a patient's constitutional right to reject unwanted treatment.

In sum, the hospital and provider are obligated to honor this patient's clear wishes. But they retain the option to seek judicial review before implementing the decision.

Q ***6. Does the prior decision clause apply to decisions by patients who have capacity?***

A No. Nothing in the FHCDA governs decisions by patients with capacity.

D. Decision-making Standard (Revised September 21, 2010)

Q ***1. Does a surrogate need clear and convincing evidence of a patient's wishes to make a decision to direct the withdrawal of life-sustaining treatment?***

A No. Indeed, a key purpose of the FHCDA was to eliminate the clear and convincing standard for clinically appropriate end-of-life decisions. Under the FHCDA, the surrogate must make the decision based on the patient's wishes "if reasonably known" or else based on the patient's best interests. There is no requirement that the surrogate specifies on what basis he /she is making the decision for the patient. However, if a hospital has reason to believe that the surrogate is not acting in good faith or is making decisions which are clearly contrary to the patient's known wishes or best interests, then the hospital should not necessarily follow the surrogate's decision. It may instead opt to convene its informal mediation, consultation or ethics process, or convene the Ethics Review Committee.

Q ***2. Do the FHCDA clinical criteria for the withdrawal of life-sustaining treatment apply to the entry of DNR orders? Do they replace the clinical criteria that were in the DNR Law?***

A Yes and yes. For any decision made after June 1, 2010, a surrogate decision to enter a DNR order must be based on the new clinical criteria. In practice, there are unlikely to be many cases where a DNR order could be entered under one law, but not under the other.

Q ***3. Do DNR orders that predate the FHCDA and were based on the former criteria need to be re-issued?***

A They do not have to be re-issued.

Q ***4. The FHCDA provides that a surrogate may consent to the withdrawal of life-sustaining treatment if one of two standards is met. The first standard requires a determination that "treatment would be an extraordinary burden to the patient." Who makes that determination? The surrogate or the attending physician***?

A The statute is not specific on this point, but it appears to be the surrogate, although the surrogate certainly should make such determination in consultation with the physician. The relevant clause states as follows:

> Decisions to withhold or withdraw life-sustaining treatment. In addition to the standards set forth in subdivision four of this section, decisions by surrogates to withhold or withdraw life-sustaining treatment shall be authorized only if the following conditions are satisfied, as applicable:
>
> (a)(i) Treatment would be an extraordinary burden to the patient and an attending physician determines, with the independent concurrence of another physician, that, to a reasonable degree of medical certainty and in accord with accepted medical standards,
>
> (A) the patient has an illness or injury which can be expected to cause death

> within six months, whether or not treatment is provided; or
>
> (B) the patient is permanently unconscious;…

By specifying the part of the determination that the physicians have to make, subparagraph (i) implicitly leaves it up to the surrogate to make the other part of the determination.

Second, a determination regarding the burden of the treatment to the patient is a subjective determination that does not appear to belong principally to the physician. In fact, the Task Force, in *When Others Must Choose*, made it clear that it is the surrogate who determines "the benefits and burdens of treatment" (p.62). It also emphasized that the concept of "excessive burden" should be understood to reflect the past values, wishes, and preference of the patient (p113), which suggests a surrogate decision.

Nonetheless, the decision about burden warrants participation and input from the physician and a dialogue between the surrogate and the physician about the decision.

Q **5.** ***Turning to the second standard, who determines whether a treatment would be "inhumane or extraordinarily burdensome"?***

A The clause with the second standard allows the withdrawal or withholding of life-sustaining treatment in the following circumstances:

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

Like the first standard, this second standard requires an assessment of the burden to the patient, and then a clinical determination regarding irreversibility which is clearly assigned to the physician. It therefore seems that the similar structure of subparagraphs (i) and (ii) indicate a similar division of responsibility—the surrogate decides whether the treatment would be "inhumane or extraordinarily burdensome" and the physician determines whether there is an irreversible condition. This interpretation would also be consistent with the Task Force's view of the subjective and non-clinical nature of a burden determination.

Moreover, the statute requires the physician's judgment to be made "to a reasonable degree of medical certainty and in accord with accepted medical standards," standards that are inconsistent with a subjective judgment about the burden of treatment. Finally, the statute requires Ethics Review Committee approval when a general hospital attending physician "objects to a surrogate's decision under" the inhumane/extraordinary burden standard to withdraw nutrition and hydration.

But as stated previously, the statute is not specific on this point; the statute simply requires that the conditions are satisfied. Also, as stated previously, the decision about burden warrants participation and input from the physician.

Q **6.** ***What qualifies as an "irreversible or incurable condition"?***

A The statute does not define the phrase, or explain it further, but from the context, purpose and background it is clear that the phrase relates to medical conditions that are severely debilitating as well as irreversible and incurable. As the Task Force wrote in *When Others Must Choose* (p. 112):

> Other Cases—Decisions to forego life-sustaining treatment may also be appropriate for some patients who are neither terminally ill nor permanently unconscious. For example, an aggressive and painful course of chemotherapy might extend the life of a patient with a chronic degenerative illness who has irreversibly lost the ability to speak or to recognize people. A surrogate might decide that the chemotherapy would be excessively burdensome to the patient, based on the patient's prior wishes or an assessment of the patient's interests.
>
> Decisions to forgo life-sustaining treatment for patients who are neither terminally ill nor permanently unconscious require heightened scrutiny....

V. Decisions About Life-Sustaining Treatment for Minor Patients (§ 2994-e)

Q **1.** ***This section provides that if a minor has decision-making capacity, then a parent's decision to withhold or withdraw life-sustaining treatment may not be implemented without the minor's consent. The former DNR had required the minor's "assent." Is there a difference?***

A No. Under either law, the minor must agree and the decision cannot go forward without the minor's approval if the minor shows an ability to understand and appreciate the treatment decision issues in question.

VI. Health Care Decisions for Adult Patients Without Surrogates (PHL § 2994-g) (Revised September 21, 2010)

Q1. ***Under the former DNR law, a DNR order could be entered for an incapable patient who did not have a surrogate if the physician and a concurring physician determined that resuscitation would be "medically futile" (i.e., if CPR would "be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs"). Can a physician still do that?***

A The language of the standard has changed, but it still ordinarily supports the entry of a DNR order if resuscitation would be "medically futile" as defined above. Under the FHCDA, the physician and a concurring physician would need to determine that (i) attempted resuscitation (in the event of arrest) would offer the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the attempt would violate accepted medical standards.

VII. DNR Orders (PHL § 2994-1)

Q1. ***The FHCDA does not include a clause from the prior DNR law that patients who do not have DNR orders are "presumed to consent to the administration of cardiopulmonary resuscitation in the event of cardiac or respiratory arrest." Former PHL § 2962.1. Does that mean there is no longer such a presumption? And does that mean that DNR orders can be written without consent?***

A No and no. The clause in the prior DNR law simply reflected the principle that in an emergency a patient is presumed to consent to necessary treatment, unless there was a prior objection to such treatment. That principle is still supported by statute and case law: patients are still presumed to consent to potentially beneficial CPR in the event of cardiac arrest unless there is a DNR order.

Q2. ***The former DNR law had a provision governing consent to a DNR order by a patient with capacity. Among other things, it set forth witnessing requirements for such consent. There does not seem to be any similar provision in the FHCDA. So what are the current requirements for consent by a capable patient to a DNR order?***

A The FHCDA repealed the former DNR law provision governing consent to a DNR order by an adult patient in a general hospital or nursing home, and did not replace it with a parallel clause in the FHCDA. As a matter of constitutional and common law, it is clear that a patient with capacity can consent to a DNR or DNI order, just as a patient with capacity can direct the withdrawal or withholding of other life-sustaining treatments. Under State health regulations, hospital patients and nursing home residents have a right to refuse medication and treatment after being fully informed and understanding the probable consequences of such actions. Hospitals and nursing homes may document such decisions in the manner they would document any consent by a patient to the withholding of life-sustaining treatment.

Q3. ***The FHCDA does not include a clause from the prior DNR law that allowed "therapeutic exception" to the requirement to secure the consent of a patient with capacity. That is, it allowed a DNR order to be issued based on a surrogate's consent rather than the patient's consent when doctors agreed that the discussion about DNR would be harmful to the patient. Was that omitted deliberately? Can a surrogate still consent to a DNR order on behalf of a capable patient?***

A The "therapeutic exception" provision was deliberately omitted from the FHCDA, and a surrogate may no longer make a DNR decision for a patient who has capacity.

VIII. Implementation and Review of Decisions (PHL § 2994-k) (Revised September 21, 2010)

Q1. ***Are DNR orders still required to be reviewed by an attending physician in hospitals every 7 days and in nursing homes every 60 days? If not, how often are they required to be reviewed?***

A The DNR law, including its specific time frames for reviewing the orders, no longer applies to hospitals and nursing homes. Instead, the FHCDA requires facilities to devise their own policies regarding review of such orders, and other life-sustaining treatment decisions. Thus a hospital or nursing home policy could continue to follow the former DNR Law review periods, or alter the review periods, or even require the attending physician to set forth a review period for patients on a case-by-case basis. DNR decisions should be treated like every other decision to withhold or withdraw life-sustaining treatment. If regular medical review is medically indicated, then it should be done.

Note that nonhospital DNR orders must be reviewed every 90 days. (See PHL § 2994-dd(4)). This is the same period as was required under the former § 2977(8).

IX. Interinstitutional Transfers (PHL §§ 2994-l, 2994-ff)

Q1. ***If a patient is admitted to a hospital with a DNR order that was issued in another hospital or nursing home or a nonhospital DNR order, can the attending physician issue an order to continue the DNR order?***

A The order that arrived with the patient remains effective until an attending physician examines the patient. That physician must then continue the order, unless the physician determines that the order is no longer appropriate or authorized. In deciding whether the order is still appropriate, the physician should consider whether the difference in response time to a cardiac arrest in the hospital might mean that the prognosis following CPR for the patient would be different, and whether a discussion with the decision-maker for the nonhospital order is warranted. Before canceling the order, the attending physician must make reasonable efforts to notify the person who made the decision. If such notice cannot reasonably be made prior to canceling the order, the attending physician must make such notice as soon as reasonably possible after cancellation.

Q2. ***When a patient in a hospital with a DNR order is transferred to a nursing home, does the nursing home need to get the resident's or surrogate's consent again to re-enter the DNR order? Will the nursing home ever have to get that consent?***

A The FHCDA provides that the attending physician at the nursing home can enter the DNR order without having to get another consent. The nursing home will never have to get that consent, unless the DNR order is revoked or suspended, and the issue is whether to enter it again.

X. Ethics Review Committees (PHL § 2994-m)

Q1. ***Are decision by the Ethics Review Committee (ERC) advisory or binding?***

A Recommendations and advice of the ERC are advisory and nonbinding, except in three limited circumstances:

(i) In a nursing home, ERC approval is required before a surrogate will have the authority to refuse life-sustaining treatment under the standard that applies to residents who are not terminally ill or permanently unconscious (but this is not applicable to DNR decisions);

(ii) In a general hospital, if the attending physician objects to a surrogate's decision to withdraw or withhold artificial nutrition and hydration based on the standard that applies to patients who are not terminally ill or permanently unconscious, the decision cannot be implemented until the ERC determines that the decision meets surrogate decision-making standards; and

(iii) A decision by an emancipated minor (without the consent of a parent or guardian) to have life-sustaining treatment withdrawn or withheld must be approved by the ERC.

Q2. ***Is it mandatory or recommended in the Act for at least for one committee member to be a person from the community (a person that has no obligation to the facility)?***

A It is mandatory.

Q3. ***Our hospital has a large ethics committee that now mostly does retrospective case review and policy review. Should that be the FHCDA ethics review committee?***

A Not necessarily. The FHCDA ethics review committee needs to be lean enough to respond to cases in real time. It might be preferable to designate a 5-7 person body for that purpose.

Q4. ***Who appoints and removes the members of the committee?***

A The hospital or nursing home can decide this, and should set it forth in its policy.

Q5. ***Are there quorum requirements? Voting rules?***

A The hospital or nursing home can decide these matters, and should set its rules in its policy.

Q6. ***What does the FHCDA mean by requiring that the committee "must include at least five members who have demonstrated an interest in or commitment to patient's rights or to the medical, public health, or social needs of those who are ill"? Does it require five members in addition to other members who meet the other qualifications?***

A The FHCDA does not require five members with a "demonstrated interest" in addition to other members who meet other qualifications. The law requires that a doctor and nurse serve on the committee and they would certainly meet the "demonstrated interest" test. Rather, the clause should be read to mean (1) that the committee must have at least five members, AND (2) those five members should have some background in the issues the committee will face (e.g., they should be health care professionals, health care advocates, persons with

significant experiences as patients or patient's family members, and other persons with a demonstrated interest or involvement in the issues.) A committee may also have members who have no record of involvement in the interests of patients. But at least five members should have that record.

Q ***7. Does the ERC displace the role of an existing ethics consultation service? Or for that matter, of the attending physician, social worker or chaplain in attempting to resolve disputes?***

A No. The FHCDA expressly recognizes that facilities may first use less formal means to attempt to resolve disputes. Those other means may include already existing ethics subcommittees and ethics consultation services. The FHCDA expressly recognizes that facilities may use less formal means first to resolve disputes. However, if a person connected with the case requests a review by the ERC, it must be provided regardless of whether less formal means have yet been exhausted. So the committee should not be regarded as an alternative to arranging a meeting between the care team and the family, or seeking an ethics consultation.

XI. Rights to Be Publicized (PHL § 2994-u)

Q ***1. The FHCDA requires hospitals and nursing homes to distribute to patients and residents a statement of their rights under the FHCDA. Where can one find that statement?***

A Hospitals should distribute the revised version of DOH publication 1449, "Your Rights as a Hospital Patient in New York State," which in any version revised May 2010 or later includes the section "Deciding About Health Care: A Guide for Patients and Families." Nursing Homes should distribute DOH publication 1503, "Deciding About Health Care: A Guide for Patients and Families." Both are available on the DOH website, as well as on this NYSBA Information Center website.

Q ***2. Do hospitals and nursing homes have to provide the PHL § 2994-u statement to current inpatients/residents?***

A DOH has taken the position that hospitals did not have to provide the statement to already admitted inpatients on June 1, 2010, but nursing homes do have to provide the statement to all of their nursing home residents, even those who were admitted before June 1, 2010.

Q ***3. Does the statement need to be provided to the patient or resident if the patient or resident lacks decision-making capacity?***

A No, in that case the statement should not be provided to the patient or resident; it should be provided to whoever has authority to make health care decisions for the patient or resident.

XII. Nonhospital DNR Orders

Q ***1. Why did Chapter 8 create a new Article 29-CCC relating to nonhospital DNR orders?***

A Previously, nonhospital DNR orders were governed by a section of PHL Article 29-B—Orders Not to Resuscitate. But Article 29-B was amended to make it apply only in mental hygiene facilities. As a result, there was a need to create a new place to preserve the law on nonhospital DNR orders.

Q ***2. Does the new provision on nonhospital DNR orders differ much from the prior nonhospital DNR provision?***

A The main difference is that surrogate consent is now governed by the standards in the FHCDA, not those in the former DNR law. Also, the prior law directed only emergency medical service personnel and hospital emergency services personnel to honor nonhospital DNR orders. The new provision also directs hospice and home care services agency personnel to honor such orders.

Q ***3. The new nonhospital DNR provision states that consent by a surrogate for a patient in a mental hygiene facility is now governed by PHL Article 29-B—Orders Not to Resuscitate in Mental Hygiene Facilities. But what if the patient is eligible for a family member to make the decision under SCPA § 1750-b?***

A OPWDD has taken the position that the family member would make the decision under the standard set forth in SCPA § 1750-b, and not the standard PHL Article 29-B.

Q ***4. Can a FHCDA surrogate consent to a nonhospital DNR order?***

A Yes.

Q ***5. Can a FHCDA surrogate consent to a nonhospital DNI order using MOLST?***

A PHL Article 29 CCC is ambiguous on this point, but DOH's answer to this question is yes. Nonhospital DNR orders can also be issued on the standard form available on the DOH website.

Q ***6. Can a FHCDA surrogate consent to other nonhospital medical orders (medical orders other than DNR/DNI) under Article 29 CCC?***

A No, but the surrogate and others may have clear and convincing evidence of the patient's wishes. And that evidence may be documented, including on a MOLST form.

Q 7. ***Under the former PHL § 2977(4), the parent or legal guardian of a minor could consent to a nonhospital DNR order for the minor, but under PHL § 2994-cc, there is no provision for consent by the parent or legal guardian or a minor. Can a parent or legal guardian of a minor still consent to a nonhospital DNR order (or a nonhospital DNI order using the MOLST form)?***

A Yes, in enacting Laws of 2010, chapter 8, there was no intent to take away the ability of the parent or legal guardian of a minor to consent to a nonhospital DNR order for the minor. A DNR or DNI order is a medical order signed by a physician, and the parent or legal guardian of a minor can consent to a medical order to provide comfort measures only (palliative care) for the minor under PHL § 2504(2). When a DNR order is signed by a physician, that is not a case where the minor is receiving no medical treatment (see, Matter of Hofbauer, 47 NY2d 648). The parent or legal guardian of a minor can consent to nonhospital DNR or DNI orders in the same manner that they would consent to them under FHCDA.

XIII. Orders Not to Resuscitate for Residents of Mental Hygiene Facilities (Chapter 8, § 22)

Q 1. ***Why did Chapter 8 amend the former DNR Law (PHL Article 29-B) to make it apply only to mental hygiene facilities?***

A Because the new FHCDA now governs DNR orders in hospitals and nursing homes, but there was a need to continue the applicability of the former DNR law to mental hygiene facilities.

XIV. Health Care Proxy Law (Chapter 8, §§ 23-24)

Q 1. ***Did Chapter 8 amend NY's Health Care Proxy Law? How?***

A Yes. Chapter 8 amended NY's Health Care Proxy Law in three ways. First it added a provision to protect institutional and provider conscience rights with respect to health care agent decisions to the same extent that the FHCDA recognizes such rights with respect to surrogate decisions. Second, it added a clause, similar to one in the FHCDA, that basically states that if an agent directs the provision of life-sustaining treatment, a hospital or provider that does not wish to provide such treatment must nonetheless comply with the agent's decision pending either transfer of the patient to a willing hospital or individual provider, or judicial review. Finally, the definition of life-sustaining treatment is amended to conform to the FHCDA definition.

Q 2. ***Can a health care agent now make decisions regarding artificial nutrition and hydration even if the patient's wishes are not reasonably known?***

A No, the health care proxy law still provides that the agent can only authorize the withdrawal of artificial nutrition and hydration based on the patient's wishes, if reasonably known, and not on the patient's best wishes if the patient's wishes are not reasonably known. This restriction is hard to reconcile with the FHCDA, which allows a surrogate to make decisions on any treatment, including artificial nutrition and hydration, based on the patient's wishes if reasonably known, or else the patient's best interests. However, in many instances a health care agent may be able to act as the surrogate for purposes of decisions regarding artificial nutrition and hydration. In the future, the Legislature should amend the Health Care Proxy Law to eliminate the disparity.

Meanwhile, it is useful to note that a health care agent does not need "clear and convincing evidence" of the patient's wishes to authorize the withdrawal of artificial nutrition and hydration; nor does the law require that the patient's wishes be in writing. The patient's wishes only need to be "reasonably known."

XV. MHL Article 81 Guardianship Law (Chapter 8, §§ 23-24)

Q 1. ***Did Chapter 8 amend NY's MHL Article 81 Guardianship Law? How?***

A Yes. Chapter 8 amended the Guardianship Law to authorize an MHL Article 81 guardian of the person to act as a surrogate under the FHCDA for decisions in hospitals. It also repeals a provision in MHL Article 81 that restricted the authority of a guardian to make life-sustaining treatment decisions.

Q 2. ***Do existing MHL Art 81 guardians automatically gain the authority of FHCDA surrogates, or does a court have to give them that authority?***

A An MHL Art. 81 guardian who had been given authority to make medical treatment decisions for the incapacitated person should now be regarded as having the authority of a surrogate. A guardian who was not given such authority would not be considered a surrogate (unless the guardian qualifies as a surrogate under another basis).

XVI. SCPA § 1750-b Guardianship (The Health Care Decisions Act for Mentally Retarded Persons) (Chapter 8, §§ 23-24)

Q 1. ***How did Chapter 8 amend the Health Care Decisions Act for Mentally Retarded Persons (SCPA § 1750-b)?***

A Chapter 8 amended SCPA § 1750-b to insert a definition of "life-sustaining treatment." It also amended § 1750-b to allow the Willowbrook Consumer Advisory Board to act as the HCDA guardian for class members.

XVII. Model Hospital and Nursing Home FHCDA Policies and Forms; MOLST

Q 1. ***I heard there are model hospital policies and forms to implement the FHCDA. Where did they come from, and where can one find them?***

A Several NYS health care associations have provided Model Hospital and Nursing Home FHCDA Policies and Forms as a service to their members, to assist facilities to implement the law.

The Model FHCDA Polices and Forms were created for the associations by (or in the case of GNYHA were based on materials created by) Tracy Miller, Esq., former Executive Director of the Task Force on Life and the Law, and Robert N. Swidler, Esq., former General Counsel to the Task Force and current Counsel to Northeast Health in Troy, NY.

To obtain the model forms or policies (members only), or for more information about them, contact one of the following associations:

- Greater New York Hospital Association (GNYHA) www.gnyha.org
- Healthcare Association of New York State (HANYS) www.hanys.org
- NYS Association of Homes and Services for the Aging (NYAHSA) www.nyahsa.org
- NYS Health Facilities Association (NYSHFA) www.nyshfa.org
- Southern New York Association (SNYA) www.sny.org

Q 2. ***What is MOLST? Can MOLST be used to document a surrogate's decision pursuant to the FHCDA as well as the resulting order?***

A MOLST (Medical Orders for Life-Sustaining Treatment) is a medical order form that can be used to set forth with helpful specificity the types of life-sustaining treatment that should or should not be provided to a patient, based on the patient's or surrogate's prior decisions.

Q 3. ***Then what is the difference between the model forms distributed by the associations and the MOLST form?***

A There is considerable overlap between the Model FHCDA Forms and MOLST. However, they differ in some important respects of substance and style:

The Model FHCDA Forms were designed to help hospitals and nursing homes meet the requirements of the FHCDA. So, for example, there is a model form to designate a surrogate to give consent to treatment per the FHCDA, as well as another form for a surrogate to consent to the withdrawal or withholding of life-sustaining treatment per the FHCDA. There is also a form to secure the attending physician's decision to provide major medical treatment to a patient who lacks capacity and does not have a surrogate, per the FHCDA.

MOLST, in contrast, relates only to life-sustaining treatment decisions. However, MOLST—unlike the Model FHCDA Forms—can be used to document life-sustaining treatment decisions outside the scope of the FHCDA, such as decisions by a patient with capacity, and decisions by a health care agent, as well as life-sustaining treatment decisions by a surrogate per the FHCDA. MOLST can also be used to document nonhospital DNR orders.

Q 4. ***So which form should a hospital or nursing home adopt?***

A Hospitals and nursing homes are free to use the Model FHCDA Forms, MOLST, some combination of them, or neither. Their obligation is to comply with the requirements of the FHCDA and other laws, not to use any particular forms.

However, whatever forms a hospital or nursing home chooses to create for its own patient and residents, its staff should become familiar with MOLST, and honor such forms when they show up with a patient.

Endnote

1. This document is the September 9, 2010 version of a document that appears on the NYS Bar Association Family Health Care Decisions Act Information Center, www.nysba.org/fhcda. It is reprinted here with the permission of the NYS Bar Association. Readers are encouraged to check the FHCDA Information Center from time to time for updates, which are marked.

Honoring Patient Preference at the End of Life: The MOLST Process and the Family Health Care Decisions Act

By Karen Lipson and Jonathan Karmel

Introduction

Patient self-determination and informed consent are fundamental elements of medical care in the United States. When a patient loses the capacity to make medical decisions, securing informed consent and carrying out the patient's wishes raise complex legal and ethical issues. These issues are particularly challenging when the patient is near the end of life and decisions must be made about whether or not to provide life-sustaining treatment. Advances in medical care in the last fifty years have enabled us to prolong life where death was once imminent, but often cannot promise an acceptable quality of life. As a result, patients and family members today face difficult choices about how they will live and die.

Since the late 1980s, New York State and the federal government have sought to encourage patients with advanced, life-limiting conditions to make decisions concerning life-sustaining treatment in advance so that, in the event that they lose decision-making capacity, their wishes can be honored. Enacted in 1990, New York's health care proxy law provides a mechanism for competent adults to appoint health care agents to make medical decisions on their behalf in the event that they lose the capacity to make those decisions. The federal Patient Self-Determination Act, enacted in 1991, requires hospitals, nursing homes, hospice programs and home health agencies to inform patients upon admission about their decision-making rights, ask them about advance directives, such as health care proxies and living wills, and document those directives in their medical records.[1]

Despite these efforts, studies have shown that the majority of seriously or terminally ill patients lack advance directives.[2] Moreover, the evidence suggests that the treatment people receive at the end of life is different from the treatment they would have requested, and often the care received is more aggressive than they would have wanted. Opinion polls indicate that a sizeable majority of patients would prefer to die at home.[3] Yet, approximately one in five Americans dies in an intensive care unit, and almost one-third die in a hospital.[4] Another 22 percent die in a nursing home.[5] According to the Dartmouth Atlas on Health Care, Medicare beneficiaries in New York have the highest rate in the U.S. of inpatient days during the last six months of life—15.5 days per deceased patient.[6] Even among Medicare beneficiaries with advanced cancer, the rate of hospital deaths is surprisingly high. About 29 percent die in a hospital, and only about half receive hospice care.[7] The rate of hospital deaths for these patients was the highest in the Manhattan hospital referral region, while hospice use in that region was significantly lower than the national average.[8]

In the absence of advance care planning and an advance directive, when a patient loses decision-making capacity, health care providers and family members often struggle mightily to make treatment decisions consistent with the patient's wishes and values and with New York's laws governing informed consent. Often these difficult decisions are made in the midst of a crisis with little opportunity for reflection. Futile and burdensome treatment may be provided, or life-sustaining treatment may be withheld, without a clear understanding of what the patient would have wanted, causing distress and guilt for family members.

Until June 2010, when an adult patient in New York lacked capacity to make medical decisions and had not appointed a health care agent or executed a living will, family members were legally authorized to consent only to a do not resuscitate (DNR) order. Decisions to withhold other life-sustaining treatment, such as artificially administered nutrition or hydration, could be made only with clear and convincing evidence of the patient's wishes or pursuant to a court order. As a result, patients near death sometimes languished in hospitals receiving futile treatment that family members knew the patient would not want. With the enactment of the Family Health Care Decisions Act (FHCDA),[9] effective June of 2010, family members and close friends can be surrogates with authority to make any treatment decision on behalf of a patient who lacks capacity. While FHCDA facilitates health care decisions for vulnerable patients, it will not succeed in promoting patient autonomy unless prospective surrogates are familiar with their loved one's goals for care, treatment preferences, and values. This can be accomplished through effective advance care planning.

Even when an advance directive is completed, if it does not transition with the patient between health care settings, it may be ineffective in assuring that the patient's care reflects his or her wishes and values. Between 25 and 30 percent of dying patients are cared for in three or more settings in the last months of life.[10] In addition, advance directives may not be implemented properly if they are not discussed with the patient's family members in advance

of a crisis. Absent these discussions, an advance directive may be too vague to provide effective guidance to clinicians and family members when the need for a decision arises. In a 2008 report to Congress, the U.S. Department of Health and Human Services concluded that many of the barriers to effective advance care planning could be addressed through adoption of the POLST (Physician Orders for Life-Sustaining Treatment) process:

> Encouraging additional POLST efforts that translate chronic care patient's [sic] care goals into easily identifiable, portable and renewable medical orders that follow the patient across settings would go a long way toward enhancing advance care planning in this country.[11]

POLST, known in New York as "MOLST" (or Medical Orders for Life-Sustaining Treatment), is a national model for advance care planning that supports shared, informed decision making, portability of advance directives across health care settings, and continuity of care.

This article will discuss how the MOLST process works, the law governing decisions to withhold and withdraw life-sustaining treatment in New York State, and the legal basis for the MOLST process. It will describe how the enactment of FHCDA has affected MOLST. Finally, it will describe the MOLST legal checklists developed by the New York State Department of Health (DOH), and the applicable law for patients in facilities licensed by the Office for People With Developmental Disabilities (OPWDD) and the Office of Mental Health (OMH).

The MOLST Process

New York's MOLST process is based on the POLST Paradigm Program initiated in the mid-1990s. Approximately 25 states have active or developing POLST programs. In another seven states, POLST has been adopted at the local or regional level.[12]

With the goal of providing patient-centered care and shared decision making, POLST provides a structured framework for conversations between physicians and their patients (or the patient's authorized decision-maker) concerning prognosis, the benefits and burdens of the life-sustaining treatment and the patient's personal goals for care. The product of the dialogue is concrete, actionable orders recorded on a portable, easily identified form. Studies have shown that POLST is useful in initiating conversations about end-of-life care, in preventing unwanted resuscitations and hospitalizations, and in documenting a range of treatment options.[13]

Ideally, a completed MOLST form is the culmination of a conversation or series of conversations between a competent patient and his or her physician and family members.[14] Although health care agents and FHCDA surrogates may consent to MOLST orders on behalf of patients who lack medical decision-making capacity, the best way to assure patient self-determination is for the patient to make these decisions while he or she has capacity to do so. Family members and/or close friends are typically included in these discussions so that they develop an understanding of the patient's goals for care and values and, in the event that the patient loses capacity, will be able to make decisions consistent with their loved one's wishes and beliefs.

After discussing the patient's prognosis, goals for care, values, options, and any prior advance directives with the patient, his or her family members, and/or close friends, the physician reviews the MOLST form (DOH-5003) with the patient and family and completes and signs it. In some physician practices and facilities, a portion of the conversation may be facilitated by a nurse or social worker; however, a licensed physician must always, at a minimum: (i) confer with the patient and/or the patient's health care agent or surrogate about the patient's diagnosis, prognosis, goals for care, treatment preferences, and consent by the appropriate decision-maker, and (ii) sign the orders derived from that discussion.

The form is bright pink so it can be found and identified easily by emergency medical services personnel responding to a call and by health care facility staff when it is placed in a medical record. The form includes specific orders concerning resuscitation, intubation, future hospitalization, artificially administered hydration and nutrition, administration of antibiotics and general treatment guidelines, such as "comfort measures only," "limited medical interventions," and "no limitations on medical interventions." The form requires the signature of the physician. Either the name or the signature of the person consenting to the orders must be included on the form. In addition, the name(s) of the witness(es) to the consent must be included on the form as well.[15]

The MOLST form is effective in the community and in health care facilities and is intended to accompany the patient as he or she transitions from one setting to another. Under FHCDA, rules governing the implementation of orders to withhold or withdraw life-sustaining treatment upon inter-institutional transfer between hospitals or nursing homes also govern non-hospital orders upon transfer to a hospital or nursing home from the community.[16] Such orders remain effective until an attending physician examines the patient, and either continues the prior orders or determines that they are no longer appropriate or authorized and cancels them.[17] Before canceling them, the attending physician must make reasonable efforts to notify the person who consented to the orders and the hospital

staff directly responsible for the patient's care. If the notice cannot be made prior to the cancellation, it must be made as soon as practicable afterwards.[18]

Although this article focuses on decisions to withhold or withdraw life-sustaining treatment, due to the complex laws surrounding such decisions, the MOLST process does not presume an outcome that limits interventions. The form includes a range of options from "attempt CPR" and "no limitations on medical interventions" to "allow natural death" and "comfort measures only." The process is not intended to limit in any way the choices of patients and families, but rather to empower them to make choices consistent with the patient's wishes, values and goals.

The Law Governing Decisions to Withhold or Withdraw Life-Sustaining Treatment in New York State

Decisions to withhold or withdraw life-sustaining treatment may be made in several different ways in New York State. A person with capacity to make medical decisions may consent to a specific medical order prior to losing capacity.[19] Or, under New York common law, health care providers may withhold or withdraw life-sustaining treatment from a patient who is dying and currently lacks the capacity to make his or her own decisions, if doing so is based upon clear and convincing evidence of the patient's wishes.[20]

Under New York's health care proxy law (Public Health Law Article 29-C), health care agents can make decisions to withhold or withdraw life-sustaining treatment even where patients have not left clear and convincing evidence of their wishes. The agent must make decisions in accordance with the principal's wishes, or if the principal's wishes are not reasonably known and cannot with reasonable diligence be ascertained, in accordance with the principal's best interests.[21]

The agent's authority to make decisions concerning the withholding or withdrawing of artificial nutrition and hydration is somewhat limited. If the principal's wishes concerning artificial nutrition and hydration are not reasonably known and cannot with reasonable diligence be ascertained, the agent does not have authority to make decisions regarding these measures.[22] However, it is not necessary to have clear and convincing evidence of a patient's wishes to satisfy the health care proxy law's standard of "reasonably knowing" the patient's wishes. Patients may explicitly state their treatment wishes on their health care proxy, in which case the health care proxy is also functioning as a living will.

When patients lack capacity, have not left clear and convincing evidence of their wishes and do not have a health care proxy, New York law authorizes specified individuals to serve as surrogates to make decisions to withhold or withdraw life-sustaining treatment discussed in more detail below. New York has allowed surrogate health care decision making for DNR orders since Public Health Law (PHL) Article 29-B was enacted in 1987. In 1991, Article 29-B added provisions for non-hospital DNR orders. DOH created the "standard form" to issue a non-hospital order not to resuscitate (DOH-3474), which is still in use today. With the enactment of FHCDA, surrogates may make any health care decision on behalf of a patient in a hospital or nursing home, including decisions to withdraw or withhold life-sustaining treatment.

The Legal Basis for the MOLST Process

In 2005, the Public Health Law was amended to give DOH authority to issue "alternative forms" for issuing non-hospital orders not to resuscitate in Monroe and Onondaga Counties. This established MOLST as a pilot program. In 2006, the law was amended to allow such "alternative forms" to be used to issue non-hospital do not intubate (DNI) orders. This was necessary because the Public Health Law makes a distinction between a DNR order and a DNI order. Under the letter of New York's Law, a DNR order only applies when a patient is in cardiac or respiratory arrest, i.e., when a patient has no pulse and/or is not breathing. Even if a patient has a non-hospital DNR order, emergency medical services personnel will still intubate a patient who has a pulse or is breathing, unless the patient also has a non-hospital DNI order.[23] In 2008, the law was amended to authorize MOLST as a non-hospital DNR and DNI order statewide.[24] MOLST is the only authorized mechanism in New York to put in place a non-hospital order that includes both DNR and DNI.[25]

Life-Sustaining Treatment Orders and MOLST Under FHCDA

Chapter 8 of the Laws of 2010, the legislation that included FHCDA (PHL Article 29-CC), made significant changes to the process for consenting to DNR orders and other orders to withhold or withdraw life-sustaining treatment. In addition to authorizing surrogate decision making in general hospitals and nursing homes for any type of health care decision, including DNR orders, it also amended PHL Article 29-B (the old DNR law) to make it applicable only to DNR decisions in certain mental hygiene facilities. It also moved the provisions for non-hospital DNR orders to a new PHL Article 29-CCC.

Under current law, the legal requirements for issuing medical orders to withhold or withdraw life-sustaining treatment differ depending on the patient, the decision-maker, and the setting where the patient is located. These requirements can be divided into eight different categories:

1. Adult Patients with Medical Decision-Making Capacity (Regardless of Setting)

Adults are presumed to have capacity to make medical decisions, unless a contrary determination has been made by a court or by the requisite health care professionals pursuant to FHCDA.[26] Adults with medical decision-making capacity have a right to consent to or decline life-sustaining treatment.[27] Prior to the enactment of FHCDA, there was a therapeutic exception to the rule that a DNR order for a patient with capacity must be based upon the patient's consent. FHCDA eliminated that exception.[28]

As explained above, adults with capacity also have the right to execute advance directives, such as a living will, to avoid getting life-sustaining treatment that they do not want after they lose capacity. A living will may not be fully effective in accomplishing this goal, because a living will may not be written with sufficient specificity to provide clear and convincing evidence of the patient's wishes. In order to provide greater assurance that their wishes will be carried out, patients can consent to medical orders for life-sustaining treatment. With the informed consent of the patient, the patient's physician can issue a variety of medical orders using DOH's MOLST form—from provide comfort measures (palliative care) only; do not attempt resuscitation (allow natural death); do not intubate (DNI); do not hospitalize; no feeding tube; no IV fluids, do not use antibiotics; to no limitations on medical interventions. Physicians may also issue other medical orders related to other life-sustaining treatments (e.g., dialysis) in the space on the form available for "other instructions."

Under FHCDA, surrogate consent is not required if the decision was expressed by the patient before the patient lost capacity "either orally during hospitalization [including during residency in a nursing home] in the presence of two witnesses eighteen years of age or older, at least one of whom is a health or social services practitioner affiliated with the hospital, or in writing."[29] The phrase "in writing" includes any legally executed non-hospital DNR order or MOLST form, even if the form was completed prior to hospitalization with the oral consent of the patient to just one witness who was the attending physician who signed the order(s).[30] However, two witnesses are recommended.

2. Adult Patients Without Medical Decision-Making Capacity Who Have a Health Care Proxy (Any Setting)

A patient without medical decision-making capacity is still presumed competent to appoint a health care agent, unless such person has been adjudged incompetent or otherwise adjudged not competent to appoint a health care agent, or unless a committee or guardian of the person has been appointed under the Mental Hygiene Law or Surrogate's Court Procedure Act (SCPA).[31]

The health care agent named in the health care proxy can consent to medical orders relating to life-sustaining treatment. If the patient's wishes are reasonably known, the health care agent must make decisions in accordance with those wishes. When there is evidence of the patient's wishes, the health care agent should still be asked to consent to the medical orders and given the opportunity to provide additional evidence of the patient's wishes. So long as the health care agent represents that he or she is acting in accordance with the patient's wishes, the health care provider should generally follow the decisions of the health care agent, unless a court has determined otherwise under PHL section 2991.

Under current law, if the principal's wishes regarding the administration of artificial nutrition and hydration are not reasonably known and cannot with reasonable diligence be ascertained, the health care agent does not have authority to make decisions regarding these measures. Health care providers may presume that patients' wishes regarding the administration of artificial nutrition and hydration are reasonably known when health care proxies state that the patients have discussed their wishes with their health care agents, and the agents know their wishes about artificial nutrition and hydration. Even if the patient's wishes regarding artificial nutrition and hydration are not known, the person named as health care agent may still have authority to make the decision as a FHCDA surrogate. It is likely that the health care agent is also highest in priority on the FHCDA surrogate list or could be designated as surrogate by a person higher in priority.[32]

Health care agents can consent to decisions to withhold or withdraw life-sustaining treatment in any setting and therefore have authority to consent to the medical orders on a MOLST form no matter where the form is completed.

3. Adult General Hospital or Nursing Home Patients Without Medical Decision-Making Capacity Who Do Not Have a Health Care Proxy, and Decision Maker Is FHCDA Surrogate

Decisions to withhold and withdraw life-sustaining treatment in a general hospital or nursing home are governed by FHCDA. Unlike PHL Article 29-B, FHCDA does not explicitly state that patients are presumed to consent to life-sustaining treatment.[33] However, FHCDA requires a number of conditions to be satisfied before life-sustaining treatment may be withheld or withdrawn. These include patient-centered decision-making standards for surrogates and clinical standards that must be verified by two physicians.[34] Unless these conditions are satisfied, life-sustaining treatment, including cardiopulmonary resuscitation (CPR), presumably must be provided.[35]

Under FHCDA, the rules for issuing orders to withhold or withdraw life-sustaining treatment in general hospitals or nursing homes have changed in a number of ways. As noted above, FHCDA authorizes surrogate decision making for all medical decisions, not just DNR decisions. Surrogate consent to a DNR order is now governed by the FHCDA rules for decisions to withhold or withdraw life-sustaining treatment. Before FHCDA, a surrogate could consent to a DNR order if the patient had a "terminal condition," which was defined as "an illness or injury from which there is no recovery, and which reasonably can be expected to cause death within one year." By contrast, FHCDA requires "an illness or injury which can be expected to cause death within six months, whether or not treatment is provided." FHCDA like the prior law, also allows surrogate consent when the patient is permanently unconscious. Under prior law, a surrogate could consent to a DNR order if resuscitation would be "medically futile," but FHCDA contains no equivalent standard for surrogate decision making. Before FHCDA, a surrogate could consent to a DNR order when resuscitation would impose an "extraordinary burden on the patient in light of the patient's medical condition and the expected outcome of resuscitation for the patient." The parallel provision of FHCDA is that "the provision of treatment would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances *and the patient has an irreversible or incurable condition*" (emphasis supplied).[36]

Since it is no longer sufficient that resuscitation is an extraordinary burden, and the patient must also have "an irreversible or incurable condition" under the extraordinary burden standard, hospitals and nursing homes will have to determine whether any of a patient's conditions can be considered "irreversible or incurable." Presumably, this term was not intended to include conditions that are literally irreversible and incurable, but are in no way debilitating. On the other hand, consider the patient who is over 100 years old and has lost medical decision-making capacity, but has no "irreversible or incurable" condition (other than the frailty that naturally accompanies old age). The application of the law to this patient is not entirely clear.

Although the law defines CPR as a type of life-sustaining treatment, it distinguishes between DNR and other orders to withdraw or withhold life-sustaining treatment, in certain circumstances. One significant difference between DNR orders and other orders to withhold or withdraw life-sustaining treatment in FHCDA is that ethics committee review is not automatically required to issue a DNR order in a nursing home under the "irreversible and incurable condition" standard, whereas ethics review committee approval is required in a nursing home to issue other orders to withhold or withdraw life-sustaining treatment under that standard.[37]

4. Adult General Hospital or Nursing Home Patients Without Medical Decision-Making Capacity Who Do Not Have a Health Care Proxy, and for Whom No FHCDA Surrogate Is Available

In limited cases, facilities may withhold or withdraw life-sustaining treatment from patients who lack medical decision-making capacity, have no health care agent, and for whom no surrogate is available. In these cases, treatment is being withheld or withdrawn without consent. A court of competent jurisdiction may make this decision. Alternatively, FHCDA provides that the facility may withhold or withdraw life-sustaining treatment if the decision is consistent with the patient's wishes, if known, or in the patient's best interests, and two physicians determine that treatment "offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided," and "the provision of life-sustaining treatment would violate accepted medical standards."[38] Before FHCDA, a general hospital or nursing home could issue a DNR order for a patient for whom no surrogate was available if CPR was "medically futile," a term that does not appear in FHCDA. Although the law now uses different words, there are probably few, if any, cases in this fourth category where a DNR order legally could have been issued before FHCDA but could not be issued under FHCDA.

5. Adult Patients Outside of a General Hospital or Nursing Home Without Medical Decision-Making Capacity Who Do Not Have a Health Care Proxy (Except Patients in Categories Seven and Eight)

Non-hospital DNR and DNI orders are now governed by the new PHL Article 29-CCC, which is derived from former PHL section 2977.[39] One difference between PHL Article 29-CCC and former PHL section 2977 is that now home care services agencies and hospices are explicitly required to honor non-hospital DNR and DNI orders. A non-hospital DNR order may be issued on the "standard form," which is DOH-3474, or the "alternative form," which is DOH-5003 (the MOLST form).[40] Non-hospital DNI orders can only be issued on the MOLST form, not on the standard form.

FHCDA surrogates have authority to consent to non-hospital DNR and DNI orders.[41] They do not have legal authority to consent to other orders to withhold or withdraw life-sustaining treatment outside of a general hospital or nursing home. Nevertheless, DOH allows the issuance of other orders to withhold or withdraw life-sustaining treatment based upon clear and convincing evidence of the patient's wishes. This is based on patients' common law and constitutional rights, as recognized in case law,[42] as well as the federal statutory right to self-determination.

6. Minor Patients

FHCDA defines a minor as an unmarried individual under eighteen years of age.[43] In general, a parent or legal guardian may consent to medical services for a minor.[44] Under PHL section 2504 and common law, parents can consent to medical orders issued by a physician that withhold or withdraw life-sustaining treatment from their children.[45] Some attorneys may be concerned that a decision to withhold or withdraw life-sustaining treatment from a terminally ill child could be construed as neglect under the Family Court Act. However, in cases involving terminally ill children and burdensome medical interventions, courts have considered parental consent to a physician's order to withhold or withdraw life-sustaining treatment, while providing palliative care to optimize the child's quality of life, a reasonable decision, not an abandonment or medical neglect of the child.[46] Indeed, the New York State Legislature has recently affirmed the legitimacy of palliative care in appropriate circumstances.[47]

FHCDA provides specific procedures that must be followed when a parent or guardian of a minor makes decisions about life-sustaining treatment in a general hospital or nursing home. Most of the provisions for a health care decision for an adult patient by a surrogate also apply to a decision by a parent for a child who lacks capacity, except that the decision only takes into account the child's wishes as appropriate under the circumstances. The attending physician must determine whether the minor has capacity, and if so, the minor must consent to the decision. Only one parent's consent is required, but health care providers must make diligent efforts to notify a second parent who has maintained substantial and continuous contact with the minor.[48] The second parent so notified has an opportunity to object to the decision before it is implemented.[49]

FHCDA does not address parental consent to the withholding or withdrawing of life-sustaining treatment outside of the hospital and nursing home settings. However, the common law provides some guidance. Before the enactment of FHCDA, in *Matter of AB*,[50] the court held that the most relevant statute should govern decisions by parents to withhold or withdraw life-sustaining treatment from minor children. Accordingly, the court applied the standards in section 1750-b of the Surrogate's Court Procedure Act, which governs surrogate decision making for persons with developmental disabilities. Now that FHCDA provides a statutory framework for decisions made by parents for children in general hospitals and nursing homes, that framework should be applied to decisions on behalf of children in the community. Just as *Matter of AB* used the standards in SCPA section 1750-b, the most relevant statute in effect at that time, decisions by parents or legal guardians of minors in the community to withhold or withdraw life-sustaining treatment should incorporate the FHCDA procedures and standards. Thus, physicians should only issue orders to withhold or withdraw life-sustaining treatment from children in the community under circumstances in which those orders would be permitted in nursing homes or hospitals.

Since the standards for nursing homes are the most stringent (specifically regarding the need for ethics committee review when decisions other than DNR are made for a patient who is neither terminally ill nor permanently unconscious), those standards should be used in the community as well. Note that in cases where ethics review committee review is needed in the community, the physician will have to find an ethics review committee willing to review the case even though the patient is neither a hospital inpatient nor a nursing home resident. In these cases, the physician would presumably have privileges at a local hospital, and that hospital's ethics review committee may be willing to review the case.

FHCDA also gives an "emancipated minor" authority to decide about life-sustaining treatment in a general hospital or nursing home.[51] An emancipated minor is a minor who is the parent of a child or is age 16 or older and living independently.[52] Although there are other instances in which a minor may consent to health care without a parent's permission or knowledge, neither FHCDA nor any other New York statute gives minors living independently general authority to make health care decisions for themselves. Also, it should be noted that FHCDA does not allow surrogates on the surrogate list to make decisions for emancipated minors who lack capacity; it only provides for health care decisions for adult patients by surrogates. Under FHCDA, however, a person under 18 years old who is married is an "adult."[53]

7. Patients with a Developmental Disability Who Lack Decision-Making Capacity and Who Do Not Have a Health Care Proxy

FHCDA does not apply to decision making for patients with developmental disabilities who lack medical decision-making capacity. Surrogate decision making for patients with developmental disabilities who lack capacity is governed by the Surrogate's Court Procedure Act (SCPA).[54] Decisions to withhold or withdraw life-sustaining treatment may be made by surrogates as provided in SCPA section 1750-b and 14 NYCRR section 633.10. Decisions by surrogates pursuant to the SCPA may be recorded in the MOLST form.[55] To assure compliance with this process, OPWDD requires that a special checklist be attached to the MOLST form.

8. Patients in a Psychiatric Unit of a General Hospital or a Psychiatric Institution Licensed by OMH Without Decision-Making Capacity Who Do Not Have a Health Care Proxy

FHCDA applies to patients with mental illness in a "general hospital," as defined by FHCDA. FHCDA, however, does not apply to decision making for patients in a ward, wing, unit or other part of a general hospital operated for the purpose of providing services for persons with mental illness pursuant to an operating certificate issued by OMH or a "hospital" as defined in Mental Hygiene Law section 1.03(10). DNR orders for such patients are still governed by the provisions of PHL Article 29-B.[56] In compliance with Article 29-B and any other applicable laws, MOLST may be used for patients with mental illness in any setting.[57]

Legal Requirements Checklists

As described above, decision-making standards and procedures for decisions to withhold or withdraw life-sustaining treatment vary depending on who makes the decision and where the decision is made. Accordingly, DOH has developed checklists that summarize these requirements in six different scenarios, along with general instructions and a glossary:

- MOLST Checklist 1—Adult with capacity (any setting)
- MOLST Checklist 2—Adult with health care proxy (any setting)
- MOLST Checklist 3—Adult with FHCDA surrogate (hospital and nursing home)
- MOLST Checklist 4—Adult without FHCDA surrogate (hospital or nursing home)
- MOLST Checklist 5—Adult without capacity in the community
- MOLST Checklist for Minor Patients and Glossary (any setting)

These checklists are not mandatory; they are intended as a tool to assist health care providers in complying with the complex laws governing decisions concerning life-sustaining treatment when completing MOLST forms.[58]

In addition, OPWDD has developed a checklist for people with developmental disabilities who lack medical decision-making capacity and do not have a health care proxy.[59] This checklist is mandatory and must be attached to the MOLST form. The use of this checklist assures that any medical decisions involving the withholding or withdrawing of life-sustaining treatment from individuals with developmental disabilities comply with the process set forth in the Surrogate's Court Procedure Act.

The DOH checklists for adults share a number of common elements. For example, they remind providers to ask patients about executing a health care proxy, if the patient has not done so and has capacity to execute one. DOH Checklists 2 through 5 set forth the appropriate process for the capacity determination, depending on whether a health care agent or an FHCDA surrogate is the decision-maker. And, they direct the physician to notify the patient of the determination of incapacity if there is any indication that the patient is able to comprehend the determination. All summarize the statutory standards for medical decision-making capacity and informed consent to life-sustaining treatment orders. And, all of the checklists remind providers of the witness requirements and the need to notify the director of the patient's correctional facility or mental hygiene facility and Mental Hygiene Legal Services, where applicable.

The DOH checklists also specify the unique requirements applicable to specific decision-makers and settings. For example, Checklist 2 (for adults with a health care proxy) alerts the provider to the two-physician capacity determination process for decisions by health care agents. It also points out the limits on the health care agent's ability to consent to the withholding or withdrawal of artificial hydration or nutrition. Checklist 3 includes both the patient-centered standards and clinical standards that must be met under FHCDA to justify the withholding or withdrawal of life-sustaining treatment when a surrogate makes that decision. Checklist 3 also points out the required ethics committee determination for decisions to withhold or withdraw life-sustaining treatment (other than CPR) in a nursing home under the "irreversible or incurable condition" standard. Checklist 4 sets forth the two alternative processes for decisions to withhold or withdraw life-sustaining treatment from a patient who lacks capacity and has neither a health care agent nor an FHCDA surrogate: (i) a court proceeding; or (ii) a determination by two physicians that treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided, and the provision of life-sustaining treatment would violate accepted medical standards.

DOH Checklist 5 delineates in detail the complex requirements for adults in the community who lack capacity and do not have a health care proxy. Checklist 5 makes clear that the authority of the FHCDA surrogate in the community is limited to DNR/DNI decisions. It also indicates that decisions concerning other life-sustaining treatment may be made based on clear and convincing evidence of the patient's wishes. "Clear and convincing evidence" is defined in the glossary accompanying the general instructions.[60]

Finally, the DOH checklist for minor patients applies to patients under age 18 who are not married. However,

it also notes that special considerations and requirements apply to decisions concerning life-sustaining treatment for emancipated minors. The checklist does not go into detail about the various considerations that apply to life-sustaining treatment decisions by or concerning emancipated minors. Instead, it directs physicians to consult with counsel regarding such decisions. As discussed above, the checklist for minor patients imports into the community setting the FHCDA requirements for withholding or withdrawing life-sustaining treatment, other than DNR, in a nursing home. It requires ethics committee review for such decisions, if the patient is neither terminally ill nor permanently unconscious. The checklist sets forth the requirements to assess the minor's capacity and secure his or her consent, if he or she has capacity. It also describes the requirements concerning notification and participation of a non-consenting parent.

It is undoubtedly challenging for busy health care providers to juggle all of these different checklists with disparate requirements. However, the checklists merely reflect the complexity of the law. And, that complexity is largely driven by a desire to protect the rights of vulnerable patients—a paramount consideration in our society. Clearly, health care providers should appreciate and consider the legal and ethical implications when issuing an order to "allow natural death."

Conclusion

MOLST and FHCDA together provide an opportunity to honor the wishes of patients and to improve the quality of end-of-life care. Widespread completion of health care proxies and MOLST forms by patients with capacity will reduce the need for decision making by FHCDA surrogates for patients approaching the end of life and will provide guidance for surrogates when needed. MOLST empowers patients in two ways. It provides a structured framework for discussions between clinicians and patients and their families about end-of-life options, so that patients have the information they need to make informed decisions. And, it provides a vehicle for patients to make clear their wishes concerning life-sustaining treatment. MOLST enables patients to communicate across care settings their desire to receive life sustaining treatment. It also makes it possible to honor the wishes of a patient to spend his or her last days comfortably at home, instead of in a hospital receiving futile and invasive interventions.

Endnotes

1. *See* 42 U.S.C. §§ 1395cc(f), 1396a(w).
2. Kass-Bartelmes, BL, Hughes, B, "Advance Care Planning: Preferences for Care at the End of Life," Agency for Healthcare Research and Quality, March 2003.
3. According to a 1999 Harvard Public Opinion Poll, 71 percent of Americans would prefer to die at home. A 2002 Harris Interactive Poll found that 86 percent of Americans believe that people who have a terminal illness would most like to receive end-of-life care at home. See also Yankelovich Partners/TIME/CNN Survey, available at http://www.libraryindex.com/pages/3165/Public-Opinion-About-Life-Death-CONCERNS-ABOUT-DEATH.html.
4. Angus, DC, Barnato, AE, Linde-Zwirble, WT, Weissfeld, LA, Watson, RS, Rickert, T, Rubenfeld, GD, "Use of intensive care at the end of life in the United States: An epidemiologic study," *Critical Care Medicine*, 32(3):638-643, March 2004. Zhao, Y, Encinosa, W, "The Cost of End-of-Life Hospitalizations 2007," HCUP Statistical Brief #81, Agency for Healthcare Research and Quality, Nov. 2009, http://www.hcup-us.ahrq.gov/reports/statbriefs/sb81.pdf.
5. Centers for Disease Control and Prevention, Nation Vital Statistics System, Deaths by place of death, age, race, and sex: United States, Worktable 309, 2005, available at: http://www.cdc.gov/nchs/nvss/mortality/gmwk309.htm.
6. Dartmouth Atlas on Health Care, End of Life Care, http://www.dartmouthatlas.org/data/region/profile.aspx?loc=34&tab=22.
7. Goodman, DC, Fisher, ES, Chang, CH, Morden, NS, Jacobson, JO, Murray, K, Miesfeldt, S, "Quality of End-of-Life Care for Medicare Beneficiaries, Regional and Hospital-Specific Analyses," Dartmouth Atlas Project, Nov. 2010, at 4.
8. *Id*. at 28.
9. L. of 2010, ch. 8, § 2.
10. "Advance Directives and Advance Care Planning: Report to Congress," U.S. Dept. of Health and Human Services, Aug. 2008, at 14, citing Brock, D, Foley, DJ. "Demography and Epidemiology of Dying in the U.S. with Emphasis on Deaths of Older Persons," in Harold, JK, Lynn, J, eds., *A Good Dying: Shaping Health Care for the Last Months of Life*, NY, NY: 1998, at 49-60.
11. *Id*. at 42.
12. Oregon State Health & Science University, Center for Ethics in Health Care, POLST, http://www.ohsu.edu/polst/.
13. Hickman, SE, Nelson, CA, Perrin, NA, Moss, AH, Hammes, BJ, Tolle, SW, "A Comparison of Methods to Communicate Treatment Preferences in Nursing Facilities: Traditional Practices Versus the Physician Orders for Life-Sustaining Treatment Program," *Journal of the American Geriatrics Society*, 58(7): 1241-1248, Jul. 2010; Hammes, BJ, Rooney, BL, Gundrum, JD, "A Comparative, Retrospective, Observational Study of the Prevalence, Availability, and Specificity of Advance Care Plans in a County that Implemented an Advance Care Planning Microsystem," *Journal of the American Geriatrics Society*, 58(7): 1249-1255, Jul. 2010; Hickman SE, Nelson CA, Moss AH et al., "Use of the Physician Orders for Life-Sustaining Treatment (POLST) Paradigm Program in the Hospice Setting," *J Palliat Med*. 12:133–141, 2009.
14. As discussed more fully below, if the patient lacks medical decision-making capacity, an appropriate FHCDA surrogate can provide consent to MOLST orders, based on specified standards, on behalf of a patient in a hospital or nursing home. In the community, surrogates may consent only to DNR and DNI orders.
15. Information for providers and consumers concerning the MOLST process is available on the Department of Health's website at http://www.nyhealth.gov/professionals/patients/patient_rights/molst/ and on the Compassion and Support website at http://www.compassionandsupport.org/index.php.
16. PHL § 2994-ff (orders pertaining to a patient admitted to a mental hygiene facility are governed by Article 29-B).
17. PHL §§ 2994-l, 2994-ff.

18. PHL § 2994-l(2).
19. *See* PHL §§ 2964, 2994-d(3)(a)(ii), 2994-cc(1).
20. *Matter of Westchester County Med. Ctr. on Behalf of O'Connor*, 72 NY2d 517.
21. PHL § 2982(2).
22. *Id*.
23. DOH Bureau of Emergency Medical Services Policy 11-02 (http://www.nyhealth.gov/nysdoh/ems/pdf/11-02.pdf).
24. L. 2008, ch. 197.
25. PHL § 2994-dd(6).
26. PHL § 2994-c(1).
27. *Matter of Storar,* 52 NY2d 363, 376.
28. *Cf.*, former PHL section 2964(3), repealed by l. 2010, ch. 8, § 9. The legislature intended to prohibit health care providers from issuing DNR orders without the informed consent of the patient, and PHL section 2805-d(4)(d) should not be interpreted to allow the "therapeutic exception." L. 2010, ch. 8 did not eliminate the principle that patients are presumed to consent to the administration of CPR in the event of cardiac or respiratory arrest. *See* PHL § 2962(1).
29. PHL § 2994-d(3)(a)(ii).
30. *See* PHL § 2994-cc(1).
31. PHL § 2981(1).
32. *See* PHL § 2994-d(1).
33. *Cf.*, PHL § 2962(1).
34. The patient-centered standards require that decisions are made "in accordance with the patient's wishes, including the patient's religious and moral beliefs" or "if the patient's wishes are not reasonably known…in accordance with the patient's best interests." The patient's best interests include: "consideration of the dignity and uniqueness of every person; the possibility and extent of preserving the patient's life; the preservation, improvement or restoration of the patient's health or functioning; the relief of the patient's suffering; and any medical condition and such other concerns and values as a reasonable person in the patient's circumstances would wish to consider." PHL § 2994-d(4). The clinical standards require a determination that (i) treatment would be an extraordinary burden, and either the patient has a terminal condition that is expected to cause death within six months, regardless of whether treatment is given, or the patient is permanently unconscious; or (ii) the treatment would be inhumane or extraordinarily burdensome and the patient has an irreversible or incurable condition. PHL § 2994-d(5).
35. *See* PHL § 2994-d; see also, PHL §§ 2805-d(2), 2504(4), 3000-a, and generally Article 30.
36. PHL § 2994-d(5).
37. PHL § 2994-d(5)(b).
38. PHL § 2994-g(5).
39. Former PHL § 2977 was repealed by l. 2010, ch. 8, § 20.
40. *See* PHL § 2994-dd(2) and 2994-dd(6).
41. PHL § 2994-cc(3).
42. *Cruzan v. Director, Missouri Dept. of Health*, 497 US 261; *Matter of Storar*, 52 NY2d 363.
43. PHL § 2994-a.
44. PHL § 2504.
45. *Matter of AB by Her Mother, CD*, 196 Misc.2d 940, 959 ["Pursuant to *Matter of Hofbauer* and Public Health Law § 2504(2), CD is authorized to make this choice for her daughter"]). Unlike former PHL section 2977, PHL section 2994-cc contains no specific provisions regarding consent by a parent to a nonhospital DNR order for a minor child. There is nothing, however, in the legislative history of l. 2010, ch. 8, to suggest any intent to take away the ability of the parent or legal guardian of a minor to consent to a nonhospital DNR order for a minor.
46. *See Matter of Hofbauer*, 47 NY2d 648, 656.
47. *See* l. 2010, ch. 331, adding PHL § 2997-c.
48. PHL §§ 2994-a(24), 2994-e.
49. PHL §§ 2994-a(26), 2994-m(2)(a).
50. 196 Misc.2d 940, 959.
51. PHL § 2994-e(3).
52. PHL § 2994-a(8).
53. PHL § 2994-a(1).
54. PHL § 2994-b(3).
55. Memo from Eileen Zibell to DDSO Directors, Voluntary Provider Agency Executive Directors regarding approval of MOLST form (January 21, 2011), http://www.omr.state.ny.us/health/hp_MOLST.jsp.
56. PHL §§ 2961(9), 2994-a(10).
57. Letter from Commissioner Michael Hogan, NYS Office of Mental Health, to Commissioner Richard Daines, NYS Dept. of Health (August 23, 2010), http://commons.wikimedia.org/wiki/File:MOLST_OMH_approval.JPG.
58. The checklists are available on the DOH website at: http://www.nyhealth.gov/professionals/patients/patient_rights/molst/.
59. The OPWDD checklist is available at: http://www.omr.state.ny.us/health/hp_MOLST.jsp.
60. "Clear and convincing evidence" is evidence that the patient held a firm and settled commitment to the withholding of life-sustaining treatment in the event of circumstances like the patient's current medical condition. The evidence may be in a written living will, and/or previous oral statements indicating the patient's wishes, considering the circumstances under which such statements were made and to whom. In order to decide whether the evidence of the patient's wishes is clear and convincing, consideration should be given to:
    - whether the statements were general or specific;
    - whether the statements were about specific circumstances (for example, terminal illness, persistent vegetative state) that are similar to the patient's current medical condition;
    - the intensity, frequency, consistency, and seriousness of such statements;
    - whether the statements tended to show that the patient held a firm and settled commitment to certain treatment decisions under circumstances like those presented;
    - whether the strength and durability of the patient's religious and moral beliefs make a more recent change of heart unlikely; and
    - whether the statements were made to one person only or to more than one person close to the patient.

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An Educational Flow Chart to Assist Physicians in Understanding the Family Health Care Decisions Act and Its Impact on Do Not Resuscitate Orders

By Lynn Hallarman, M.D.

I. Introduction

The Family Health Care Decisions Act has made both substantive and subtle changes to New York State Do Not Resuscitate (DNR) law as it applies to surrogate decision makers. Academic teaching hospitals with hundreds of medical staff, including medical trainees, are uniquely challenged in educating physicians about these changes. Major changes include: 1) **Circumstances** in which a DNR determination can be made by a physician. 2) The ability of a surrogate to request a DNR for a loved one based on "**best interest**." 3) The ability of a "**domestic partner**" to act in "best interest." 4) The expansion of health care providers beyond a physician who can make a **secondary capacity determination**. 5) The ability for a physician to **add Do Not Intubate** (DNI) with best interest consideration rather than clear and convincing evidence.

At Stony Brook University Medical Center, a flow chart[1] was developed as part of an institution-wide initiative to educate physicians on the process of entering DNR or DNR/DNI orders in hospitalized patients. The chart emphasizes the different legal standard necessary to actuate a DNR or DNR/DNI depending on if the decision maker is the 1) Patient, 2) Health Care Agent, 3) Surrogate or 4) *No* Health Care Proxy/Living Will or Surrogate. The chart was introduced to the hospital community and medical school through a series of grand round presentations and distributed widely to our training physicians, nurses and social work providers. Our flow chart is meant to be a companion guide to an institution-wide documentation form (DNR progress note) that is used for verbal consent to DNR or DNR/DNI.

Implicit to every DNR or DNR/DNI determination is the physician's prediction of CPR efficacy in a given patient based on the research literature. The strongest evidence of CPR efficacy in hospitalized patients (or survival to discharge after a cardiopulmonary arrest) comes from the *National Registry of Cardiopulmonary Resuscitation*.[2] In this prospective, multisite, observational study of 14,720 hospitalized of adult patients overall survival to discharge after a CPR attempt was 17%. This includes *all* patients who have an arrest regardless of the underlying medical illness. The arrhythmia type at the time of arrest influences survival to discharge: 34% for ventricular fibrillation, but only 10% for asystole (when the heart stops completely). In a recent retrospective study[3] of 433,985 Medicare recipients 18.3% survived to hospital discharge. Survival rate did not change over the thirteen-year study period despite improvements in CPR science and outpatient CPR survival. In a meta-analysis factors which predict failure to survive to hospital discharge after CPR included: overwhelming infection the day prior to the CPR event, kidney failure, metastatic cancer (2%-8%), dementia, and patient with dependent functional status.[4]

The Family Health Care Decisions Act (FHCDA) asks physicians to consider CPR efficacy in patients who are predicted to have less than 6 months to live (terminal), or are permanently unconscious or have an irreversible or incurable condition. The medical futility criterion of CPR, which was present in the NY State DNR Law, was deleted from the FHCDA. The FHCDA differs from the prior DNR law in that surrogate decision makers are now asked to consider the possible burden of, pain and suffering of CPR to the patient or act in their best interest rather than having a clear knowledge of the patient's preference regarding CPR. Domestic partners are now recognized for the first time in NY State Health Law in the FHCDA as surrogate decision makers. Domestic Partners are required to attest in writing that they are a permanent household member and share financial resources. Non-physicians, including nurse practitioners, physician assistants and social workers with special training, are now allowed to provide concurring determination for medical capacity. Physicians now can add DNI with DNR without clear and convincing evidence. This is particularly relevant for patients near the end of life for whom intubation puts them at high risk for a prolonged death while ventilator dependent. The FHCDA for patients with developmental disabilities or mental illness continues to require subspecialty capacity evaluations for medical decision making. At our institution, all patients with developmental disability for whom a DNR or DNR/DNI decision is being considered require a pre-screen evaluation by risk management to ensure compliance with the array of legal standards that apply to this population.[5]

Most importantly, our physicians are encouraged to address DNR/DNI as part of anticipatory goal-directed planning for patients who are highly unlikely to benefit from a CPR/intubation attempt. In instances where patients/families continue to struggle with difficult deci-

sion making, a palliative care consultation is encouraged *proactively* to avert potential conflict. For situations in which a dispute cannot be resolved through collaborative discussions between physicians, patients/families, an ethics consultation can be obtained.

II. DNR Order Flow Chart[6] and Case Examples

The following case scenarios illustrate the process for initiating a DNR or DNR/DNI order in a hospitalized patient:

Case #1: The Patient with Capacity for Medical Decision Making (MDM)

Mr. Patient is a 70-year-old man with advanced lung cancer who is receiving oral chemotherapy, and is admitted to the hospital for pneumonia that is responding to antibiotic treatment. The attending physician notes the patient has progressive weight loss, a history of overall functional decline over several months and seems frail. The attending thinks he is a good candidate for DNR/DNI as it is predicted that the patient's survival to hospital discharge after a resuscitation attempt or intubation for impending respiratory failure is very low. The attending physician speaks with the patient about his preferences regarding DNR and DNI. She meets at the bedside with the patient and his wife along with the nurse and team's resident physician. The doctors first assess his understanding of his illness and current condition and believe he has good understanding and has capacity to make a decision regarding DNR. After a ***goal setting discussion****, they explain specifically what a DNR and a DNI is, including risks and benefits, and the patient agrees to DNR and DNI. The attending then documents in the chart the discussion with the patient and who was present at the discussion. A DNR/DNI order is entered into the medical record.*

CASE #1: DNR/DNI DISCUSSION WITH A PATIENT WITH CAPACITY

Patient Has Capacity
⇓
Goal Setting/Risk/Benefit Discussion with the Patient
⇓
Documentation in the Medical Record
⇓
DNR/DNI Order Issued by Attending Physician

Case #2: Patient Who Lacks Capacity for MDM and Has a Health Care Proxy (HCP)

Mr. Patient is a 70-year-old debilitated man with oxygen dependent chronic obstructive pulmonary disease (COPD), admitted to the hospital for pneumonia. He is not doing well despite attempts to reverse respiratory failure. The attending thinks that he is at risk for a respiratory arrest and is predicted to have a very low likelihood of survival to hospital discharge after a resuscitation attempt or intubation for impending respiratory failure. The attending physician attempts to speak with him today about his preferences regarding DNR and also wants to discuss the risks of intubation and the possibility of ventilator dependency. The attending physician assesses his understanding of his illness and current condition and both the attending physician and a second team doctor concur that he is too ill to discuss DNR/DNI and lacks capacity to make a decision regarding DNR/DNI. They predict that he will not be able to discuss DNR/DNI in the near future because of acute illness and debility. The team reviews his written advance directive and finds his brother is his HCP. After a ***goal setting discussion with the brother****, they explain specifically what a DNR and a DNI is, including risks and benefits, and the HCP agrees to DNR. In addition, they discuss the possibility of impending respiratory failure and the health care agent believes that the patient "would not want to be intubated" (DNI) or "end up" ventilator dependent. The attending physician documents in the medical record the capacity evaluation, the discussion with the health care agent and who was present at the discussion. The second physician documents a separate concurring capacity evaluation. The Attending Physician enters a DNR/DNI order into the medical record.*

CASE #2: PATIENT WHO LACKS CAPACITY FOR MDM AND HAS A HCP

Concurring Lack of Capacity Assessment/ Documentation by Health or Social Service Practitioner
⇓
HCP Has Reasonable Understanding of Patient Preferences Regarding DNR/DNI or Is Acting in Best Interest
⇓
Goal Setting/Risk/Benefit Discussion with the HCP and Documentation in the Medical Record
⇓
DNR/DNI Order Issued by Attending Physician

Case #3: Patient Who Lacks Capacity for MDM Who Does NOT Have a HCP but Has a Surrogate Decision Maker (Family Health Care Decisions Act)

Mr. Patient is a 70-year-old debilitated man with end stage dementia (total care, non-verbal and bedbound) admitted for recurrent multidrug resistant aspiration pneumonia. The attending physician believes the patient has likely entered the terminal phase of his illness (< 6 months life expectancy). The attending thinks that he is at high risk for a respiratory arrest and is predicted to have a very low likelihood of survival to hospital discharge after a resuscitation attempt or intubation for impending respiratory failure. The attending physician assesses the patient's understanding of his illness and current condition and both the attending physician and a second team doctor concur that the patient lacks capacity to make a decision regarding DNR/DNI secondary to advanced dementia. They predict that he will never be able to discuss DNR/DNI. The team reviews his chart and discovers there is ***no advance directive****. His brother is identified as the appropriate* ***surrogate decision maker****. After a* ***goal setting discussion with the brother,*** *they explain specifically what a DNR and a DNI is, including risks and benefits. The brother tells the team that "his brother has been through enough" with multiple hospitalizations and progressive debility. He does not want to see him suffer with "more interventions" and agrees to DNR/DNI. The attending physician documents in the medical record: 1) the capacity evaluation, 2)* ***the necessary clinical condition*** *(terminal) met for surrogate decision making, 3) the discussion with the surrogate and who was present at the discussion. The second physician documents a separate concurring capacity evaluation, and* ***the necessary clinical condition*** *(terminal) met for surrogate decision making. The Attending Physician enters a DNR/DNI order into the medical record.*

CASE #3: PATIENT WHO LACKS CAPACITY FOR MDM WHO DOES NOT HAVE A HCP BUT HAS A SURROGATE DECISION MAKER

Concurring Lack of Capacity Assessment/ Documentation

⇓

Attending Physician Documents 1/3 Conditions Met: A. Terminal Condition B. Permanently Unconscious C. Irreversible or Incurable Condition (Second Physician Must Concur/Document)

⇓

Surrogate Has *"reasonable understanding of patient preferences regarding DNR/DNI, believes treatment would be an extraordinary burden to patient or involves pain and suffering under the circumstances, or is acting in the patient's best interest"*

⇓

Goal Setting/Risk/Benefit Discussion with Surrogate/ Documentation in Medical Record

⇓

DNR/DNI Order Issued by Attending Physician

Case #4: Patient Who Lacks Capacity for MDM Who Does Not Have a HCP or a Surrogate

Mr. Patient is a 70-year-old debilitated man with advanced lung cancer with metastatic disease to the lung, liver and brain admitted for pneumonia and acute kidney failure. He is currently in multisystem organ failure and emergently intubated for impending respiratory failure despite attempts to stabilize his condition. The attending believes he has entered the terminal phase of his illness and ***death is imminent****. The attending is worried he may have a cardiopulmonary arrest and believes he would not live through the experience. The attending attempts to speak with him today about his preferences regarding DNR. The attending physician assesses the patient's understanding of illness and current condition and both the attending physician and a second team doctor concur that the patient lacks capacity to make a decision regarding DNR secondary to severe acute illness. They predict that he will never be able to discuss DNR. They review his chart and discover there is* ***no advance directive and they have not been able to locate any family or even a friend.*** *The attending physician determines to a reasonable degree of medical certainty that CPR offers no medical benefit because patient will die imminently even if the treatment is provided, and CPR would violate accepted medical standards. The attending and the concurring physician separately document a capacity evaluation and that CPR would offer no medical benefit. The Attending Physician enters a DNR order into the medical record.*

CASE #4: PATIENT WHO LACKS CAPACITY FOR MDM WHO DOES NOT HAVE A HCP OR A SURROGATE

Concurring Lack of Capacity Assessment/ Documentation by Health or Social Service Practitioner

⇓

Attending Physician Documents Statement That *"CPR offers no medical benefit because patient will die imminently and CPR would violate accepted medical standards"*

⇓

Second Physician Must Concur/ Document

⇓

DNR Order Issued by Attending Physician

III. Conclusion

DNR or DNR/DNI orders are the most frequently used order to forgo a life-sustaining treatment either alone or as part of a plan to withdraw other life-sustaining technologies such as dialysis or ventilators. Educating physicians and other health care providers about the application of the FHCDA to DNR discussions and decisions through targeted educational initiatives is key to compliance with the law and fundamental to excellent patient care.

Endnotes

1. Stony Brook University Guide to DNR Orders.
2. Peberdy MA, Kaye W, Ornato JP, et al. Cardiopulmonary resuscitation of adults in the hospital: A report of 14,720 cardiac arrests from the National Registry of Cardiopulmonary Resuscitation. Resuscitation. 2003; 58 297-308.
3. Ehlenbach WJ, Epidemiologic Study of In-Hospital Cardiopulmonary Resuscitation in the Elderly, NEJM 2009; 361;1.
4. Ebell MH, et al. Survival after in-hospital cardiopulmonary resuscitation: a meta-analysis. J Gen Int Med. 1998; 13(12): 805-16. Zafari AM, Zarter SK; Reisfield GM, et al. Survival in cancer patients undergoing in-hospital cardiopulmonary resuscitation: a meta-analysis. Resuscitation. 2006; 71:152-160.
5. Swidler R., "Surrogate Decision Making for Incapable Adult Patients with Mental Disabilities: A Chart of the Applicable Laws and Regulations," NYS Health L J, 2011; 16(1).
6. See note 1, *supra*.

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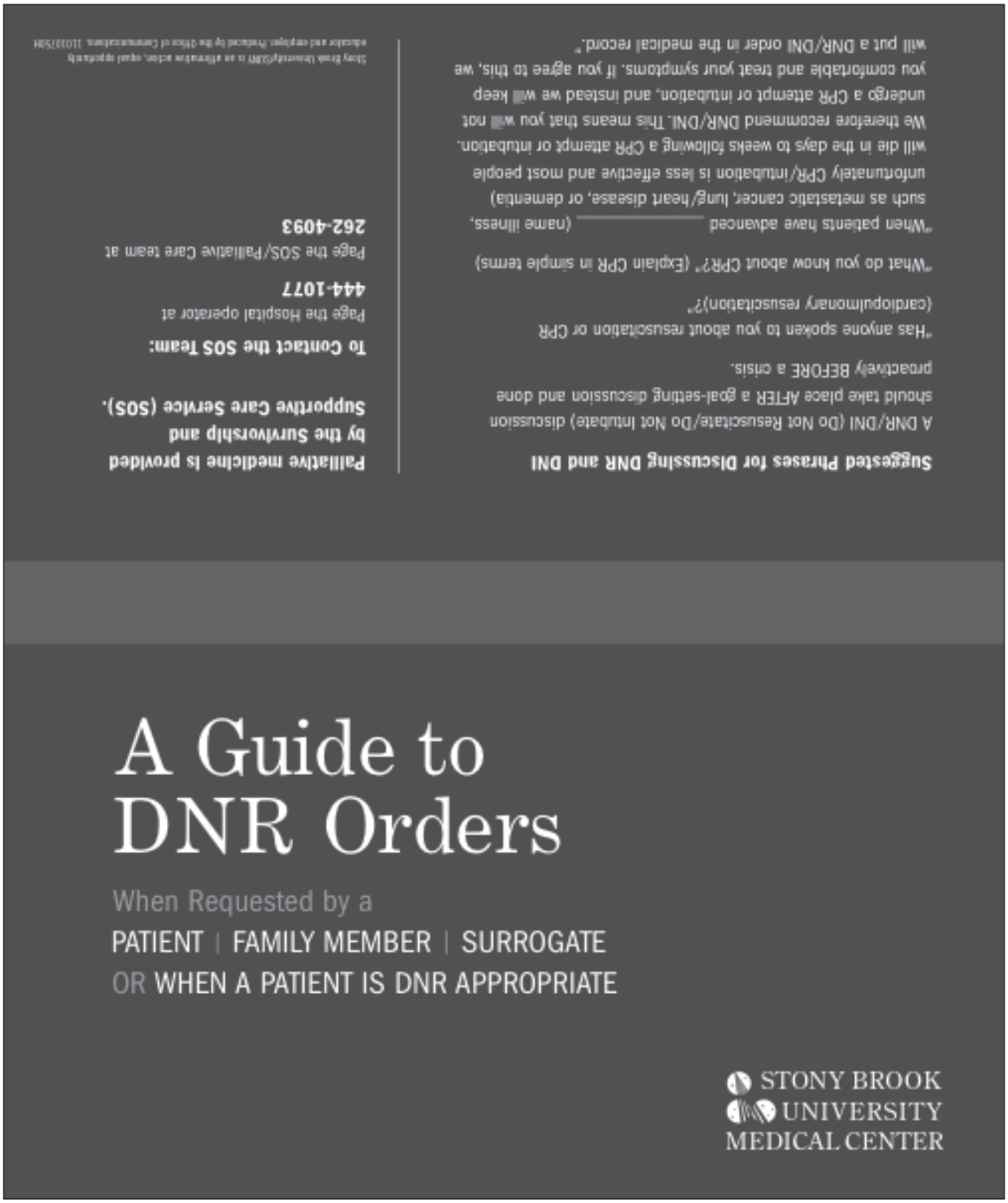

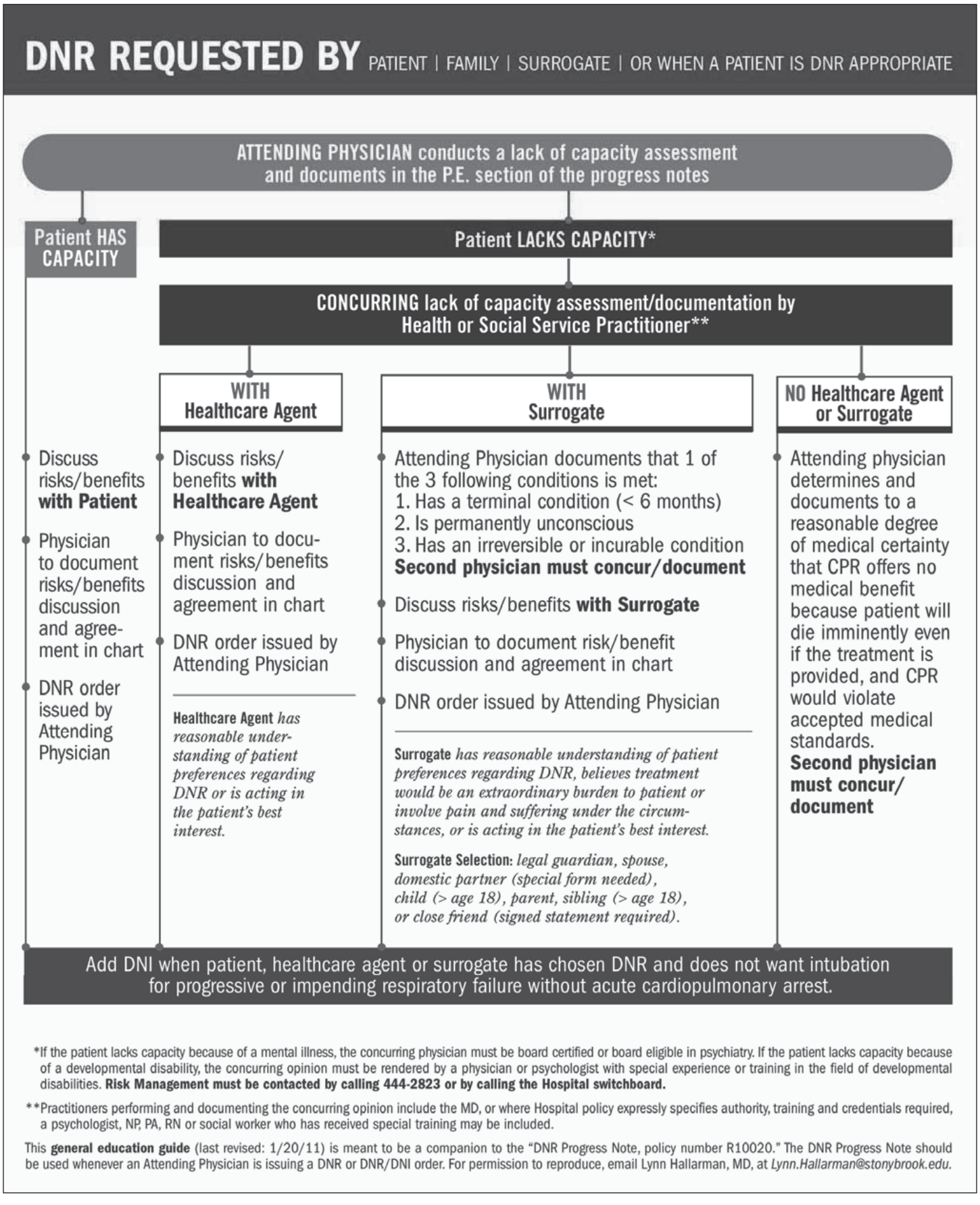

*If the patient lacks capacity because of a mental illness, the concurring physician must be board certified or board eligible in psychiatry. If the patient lacks capacity because of a developmental disability, the concurring opinion must be rendered by a physician or psychologist with special experience or training in the field of developmental disabilities. **Risk Management must be contacted by calling 444-2823 or by calling the Hospital switchboard.**

**Practitioners performing and documenting the concurring opinion include the MD, or where Hospital policy expressly specifies authority, training and credentials required, a psychologist, NP, PA, RN or social worker who has received special training may be included.

This **general education guide** (last revised: 1/20/11) is meant to be a companion to the "DNR Progress Note, policy number R10020." The DNR Progress Note should be used whenever an Attending Physician is issuing a DNR or DNR/DNI order. For permission to reproduce, email Lynn Hallarman, MD, at *Lynn.Hallarman@stonybrook.edu.*

Making the Family Health Care Decisions Act Apply to Hospice Patients

By Kathy McMahon

Introduction

The Family Health Care Decisions Act (FHCDA), first introduced in 1993, went through many iterations before it was passed and signed into law in 2010. This landmark piece of legislation sets forth a framework for surrogate decision making for patients who lack capacity and have not designated a health care proxy or established advance directives. New York is no longer one of the only states in the nation that had neither surrogate decision-making statute or case law. However, as enacted, the FHCDA authorizes surrogate decision making only in hospital and long-term care facilities.[1]

For 17 years New York State's hospices advocated for passage of the Family Health Care Decisions Act (FHCDA). Hospices regarded passage of the Act as an access issue—without FHCDA terminally ill patients who lack capacity are denied access to the hospice benefit. When FHCDA was passed and signed into law in 2010 it was a momentous event. However, FHCDA does not address surrogate decision making in hospice or for someone lacking capacity in a community-based setting to elect hospice.

Background—Hospice

Hospice is a unique model of care—it provides case management and patient-centered care using an interdisciplinary team. Patient choice is one of the hallmarks of the program, which has been a Medicare benefit since 1985. Patient choice—medical decision making—is clear cut when the patient has capacity and/or has an advance directive. However, when the patient lacks capacity, and there is no health care proxy, what happens to the patient in the community who could benefit from hospice care? Since the FHCDA is inapplicable to such patients, it ordinarily means that the patient is denied access to hospice care, which clearly was not the intent of the FHCDA.

Hospice:

- Embraces all patients coping with advanced illnesses,
- Focuses on comfort rather than cure,
- Emphasizes quality of life,
- Promotes personal choice and individual dignity,
- Respects the traditions and wishes of the patient and the patient's family,
- Most often provides care in the patient's home, but when necessary, can also provide care in the nursing home and inpatient setting,
- Utilizes current treatments and medications,
- Addresses physical, social, emotional, and spiritual needs, and
- Provides care and support to the bereaved.

In hospice the *family* is the unit of care. Each patient/family has an interdisciplinary team, comprised of: physician, nurse, home health aide social worker, pastoral care (if they wish), volunteers (if they wish) and bereavement counselors.

The process for acceptance into the hospice program is comprehensive: 1) the patient is referred to the hospice; 2) the hospice completes an evaluation to determine eligibility (6 months or less terminal diagnosis; two physicians must certify the 6-month prognosis); 3) the patient (or health care proxy) elects the hospice benefit; 4) comprehensive assessment of the patient's/family's need is completed; and 5) a Plan of Care (which is changed as needed to meet the needs of the patient and family) is developed.

The diagnoses of hospice patients include: cancers; chronic obstructive pulmonary disease (COPD), such as emphysema; cardiac diseases, e.g., congestive heart failure (CHF); Parkinson's disease; Alzheimer's and other dementias.

Challenges Faced by Hospice

The case study below clearly demonstrates why FHCDA should apply to hospice:

> *Patient, a 75-year-old man, was dying from brain cancer. His doctor, an oncologist, first raised the issue of hospice care with the patient's wife when the patient was at home and receiving home health care. At that time, the patient no longer had decision-making capacity. The patient's wife immediately recognized the value of electing hospice. She knew that her husband would prefer to die at home with palliative care, and she very much wanted to start to receive the case management and multidisciplinary support services that hospice could offer.*
>
> *Accordingly the physician referred the wife to the local hospice, and she promptly contacted that*

organization. However, the hospice administrator reluctantly informed the wife that she did not have the authority either to elect hospice for her husband, or to authorize a plan of care at home that limited life-sustaining treatment. He suggested that the wife either go to court for a guardianship, or wait until her husband was hospitalized, and then use her authority as surrogate under the FHCDA to elect hospice. The wife was dismayed, and did not take further steps to secure hospice services. Her husband died about two weeks later with far less than optimal end of life care.

If the FHCDA applied to decisions relating to hospice patients (including the decision to elect hospice), it would have been possible for care to be provided in accordance with the patient's wishes. Instead, currently this wife and many others like her do not have authority as surrogate decision-maker, and are constrained from fulfilling what they believe would have been the patient's wishes.

How Hospice Fits Within the FHCDA Structure

Hospices, like hospitals and nursing homes, are highly regulated. Hospices are Medicare-certified by the Center for Medicare & Medicaid Services (CMS)[2] and licensed by the State of New York.[3] They must operate in compliance with CMS's Hospice Conditions of Participation (COPs). New York's hospices are periodically surveyed by the NYS Department of Health's Bureau of Home Care and Hospice Surveillance and Quality Indicators/Evaluation to assure that they are in compliance with the COPs:

Quality matters! New York's hospices are committed to providing quality end-of-life care. All hospices are mandated by CMS to have a Quality Assessment and Performance Improvement (QAPI) program in place.[4] Seven New York State Hospices and palliative care providers participated in the recently completed CMS AIM (Assessment, Intervention and Measurement) grant, which charged IPRO with developing a set of recommended quality measures for hospice. Phase 2 of the NYS Department of Health's (DOH) Hospice Quality Initiative will be implemented in the near future.

Amendments to allow surrogate decision making for hospice will be an easy "fit" within the structure already established by FHCDA. Specifically, hospices can meet the FHCDA standards with respect to:

- use of ethics committees,
- process for determining capacity,
- process and procedures for end-of-life decision making, and
- decision making for the "isolated patient," i.e., a person who lacks capacity and who has no one in the hierarchy listed in FHCDA.

Next Steps

The statute that enacted the FHCDA charged the Task Force for Life and the Law with examining whether the FHCDA should be amended to apply to decisions for health care in community-based settings.[5] The Task Force's report, issued on December 22, 2010 (see Appendix A on p. 51) recommended: "…that the Legislature amend the FHCDA to include decisions regarding hospice care."[6] This is a big "win" for patients in community-based settings who are eligible for the hospice benefit but lack capacity and do not have a health care proxy. The next step is to translate the Task Force's recommendation into draft statute for introduction in the New York State Assembly and Senate.

Conclusion

State law must protect the rights of all patients, ensuring that they can live with dignity and receive care consistent with their own wishes and beliefs. It is crucial that all New Yorkers—including those being cared for outside hospital or nursing home settings—should be offered protection by the law and compassion by the courts.

Without the protections afforded by the Family Health Care Decision Act, many New Yorkers are denied access to the quality end-of-life care offered by hospice. Most family members incorrectly assume that they do have the legal right to make decisions on behalf of the patient who lacks capacity. Unfortunately, that is not the case.

We are now in year eighteen of the struggle for a health care decision-making process that supports access to hospice. Will 2011 be the year? We certainly hope so. The Task Force on Life and the Law is to be commended for their comprehensive report and thoughtful consideration of the issues. The Legislature should act quickly to adopt the Task Force's recommendations, and apply the FHCDA to decisions relating to hospice.

Endnotes

1. Public Health Law §2994-b.1.
2. See 42 CFR Part 418. CMS approves hospices for participation in Medicare after a survey by either the State or a recognized accreditation agency. The survey examines this hospice's compliance with CMS conditions of participation. See CMS State Operations Manual, chapter 2.
3. NYS Public Health Law Article 40.
4. 42 CFR §418.58.
5. NY Laws of 2010, Ch.8, §28.2.
6. NYS Task Force on Life and the Law, *Recommendations Regarding the Extention of the Family Health Care Decisions Act to Hospice,* Nov. 30, 2010. The recommendation can be found on p. 51 (Appendix A) or at http://www.health.state.ny.us/regulations/task_force/docs/2010-12-22_extension_of_family_health_care_decisions_act.pdf.

Kathy McMahon is President and CEO of the Hospice and Palliative Care Association of New York State.

APPENDIX A

NEW YORK STATE TASK FORCE ON LIFE & THE LAW
90 Church Street, 15th Floor, New York, NY 10007
Phone (212) 417-5444 • Fax (212) 417-4643

December 22, 2010

Honorable John L. Sampson
Majority Conference Leader, New York State Senate
Legislative Office Building
188 State Street, Room 409
Albany, New York 12247

Honorable Dean G. Skelos
Minority Leader, New York State Senate
Legislative Office Building
188 State Street, Room 907
Albany, New York 12247

Honorable Sheldon Silver
Speaker, New York State Assembly
Legislative Office Building
188 State Street, Room 932
Albany, New York 12248

Honorable Brian M. Kolb
Minority Leader, New York State Assembly
Legislative Office Building
188 State Street, Room 933
Albany, New York 12248

Dear Senators Sampson and Skelos, and Assembly Members Silver and Kolb:

On behalf of the New York State Task Force on Life and the Law (the "Task Force"), I am pleased to submit for your consideration, "*Recommendations Regarding the Extension of the Family Health Care Decisions Act to Include Hospice*."

The Task Force was created by Executive Order in 1985 to develop public policy on issues arising at the interface of law, medicine, and ethics. Since then, the Task Force has issued influential reports on a variety of bioethics issues, including genetic testing, assisted reproductive technologies, allocation of ventilators in the event of a pandemic influenza outbreak, and organ donation.

The Task Force commends the Legislature on the passage of the Family Health Care Decisions Act ("FHCDA") in March 2010, which provides New Yorkers with an invaluable tool to facilitate surrogate decision-making for health care. Prior to the FHCDA, families and close friends of patients did not have the authority to make even routine health care decisions on a patient's behalf, and were required to satisfy an extremely high evidentiary burden when the decision concerned the withholding or withdrawing of life-sustaining treatment. The FHCDA greatly improved this situation by authorizing surrogates to make health care decisions for loved

ones in hospitals and residential health care facilities. However, it still leaves thousands of New Yorkers who receive care in other settings and who cannot speak for themselves without the benefit of a surrogate decision-maker.

The Legislature directed the Task Force to examine whether the FHCDA should be amended to apply to decisions for health care provided in settings outside of hospitals and residential health care facilities. *See* 2010 N.Y. Laws Ch. 8, § 28 (2). Over the past several months, the Task Force has deliberated over the ethical and legal issues raised by extending the FHCDA, and is prepared to make an initial recommendation that the FHCDA should be amended to provide surrogates with authority to make decisions on behalf of incapable patients for hospice care.

In order to be eligible for hospice, a patient must suffer from a terminal illness and have a life-expectancy of six months or less. These patients' conditions often affect their ability to make choices or express wishes, precisely at a time when they face many important health care decisions. Accordingly, surrogate decision-making for these vulnerable patients is crucial to ensuring that their rights and welfare are protected, and that they live the remainder of their days in dignity and with appropriate care.

As is set forth in further detail in the accompanying document, the Task Force hereby recommends that the Legislature amend the FHCDA to include decisions regarding hospice care. In the coming months, the Task Force will continue to explore the legal and ethical dimensions of extending the FHCDA's surrogate decision-making authority to other care settings and will provide additional recommendations on these issues to the Legislature.

Thank you for your attention to this matter, and for entrusting the Task Force with this important project. We look forward to working with you in the future.

Sincerely,

Beth E. Roxland, J.D., M.Bioethics
Executive Director
New York State Task Force on Life and the Law

Enclosure

cc: Richard F. Daines, M.D., Commissioner, New York State Department of Health
Honorable Thomas K. Duane, Chair, New York State Senate Health Committee
Honorable Kemp Hannon, Ranking Member, New York State Senate Health Committee
Honorable Richard N. Gottfried, Chair, New York State Assembly Committee on Health
Honorable James G. Bacalles, Ranking Member, New York State Assembly Committee on Health

APPENDIX A (continued)

Recommendations Regarding the Extension of the Family Health Care Decisions Act to Include Hospice

New York State Task Force on Life and the Law

November 30, 2010

I. Introduction

The enactment of the Family Health Care Decisions Act ("FHCDA") in March 2010 reflects the culmination of seventeen years of advocacy and support from the health care community in New York State, and represents a landmark legislative achievement. The law establishes a framework to allow surrogate decision making for patients without capacity when they have not chosen a health care proxy or left other instructions to direct their care. The Task Force on Life and the Law ("Task Force") proposed the legislation in its 1992 report titled *When Others Must Choose: Deciding for Patients Without Capacity* and welcomed with enthusiasm its passage.

The FHCDA was designed to fill a longstanding gap in New York law by providing an invaluable tool for surrogate decision-makers to honor the wishes of patients when they cannot speak for themselves, or to act in the best interests of these patients when their wishes are unknown. Prior to the passage of the FHCDA, families and close friends of patients did not have the authority to make even routine health care decisions on a patient's behalf, and were required to satisfy an extremely high evidentiary burden when the decision concerned the withholding or withdrawing of life-sustaining treatment. As a result, surrogates did not have the ability to consent to ameliorative treatments or to object to procedures, regardless of the degree of invasiveness, which may have run contrary to their loved one's previously expressed wishes or best interests.

II. FHCDA Issues for Task Force Consideration

The scope of surrogate authority under the FHCDA currently is limited to decisions about health care provided in two specific settings: hospitals and nursing homes.[1] The Legislature explicitly assigned[2] to the Task Force the project of considering whether the FHCDA should be amended to apply to decisions for health care provided in other settings, such as hospice, home care, or doctor's offices.[3]

The Task Force began its deliberations by identifying: (1) the settings where surrogate health care decisions are likely to be necessary, and (2) the procedural safeguards required to ensure proper oversight of health care delivery and protection of patient rights in these additional sites. For the reasons discussed below, surrogate decision making in hospices emerged as a priority for early legislative action. In the coming months, the Task Force intends to continue its deliberations and issue further recommendations on the extension of the FHCDA, but is making an initial recommendation that the FHCDA be amended to include surrogate decision making in the context of hospice care.

III. Provision of Hospice Care

A. The Provision of Hospice Care in New York State

Hospice is an interdisciplinary approach to end-of-life care that emphasizes palliative treatments and comfort care rather than curative care, while simultaneously providing comprehensive support to patients and their families. Hospice care is often provided in hospitals and nursing homes, but also is routinely provided in the home and other community-based settings. Patients are not eligible for hospice care until it is determined that their condition is incurable and that they have a life expectancy of six months or less.

In order to receive hospice care, an eligible patient must "elect" to enroll in hospice.[4] Once the hospice election is made, a detailed care plan is created by the hospice team and the patient, which includes preferences and directions for withholding or withdrawing care. Therefore, health care decisions must be made both

to elect hospice and to direct the care of the patient once he or she is enrolled in hospice. When a patient lacks decision-making capacity, the family or other decision-maker must step in to make these decisions.

B. Barriers to Surrogate Decision Making Regarding Hospice Care

Patients who qualify for hospice care are an extremely vulnerable population who, by definition, are at the end of their lives. Due to complications resulting from terminal illness, many of these patients lack decision-making capacity and therefore must be able to rely on surrogate decision-makers and clinicians to ensure that they live out their final days in comfort and with dignity.

The current wording of the FHCDA creates a barrier to the utilization of hospice by terminally ill individuals because the authority it bestows upon surrogates is limited to care provided in hospitals or nursing homes. The FHCDA does not permit a surrogate to elect hospice care for a loved one who is being cared for outside of a covered facility at the time of the election decision. Even when a patient is successfully enrolled in hospice, a surrogate lacks the ability to make decisions about on-going care so long as that care is to be provided outside of a covered facility, for example, where hospice care will be provided in a stand-alone hospice facility or in the home. Therefore, the ability of a patient without decision-making capacity to access hospice care will depend upon where care is currently provided or will be provided going forward. Instead, the focus should be solely on ensuring that the individual's known preferences or best interests are honored at this crucial time.

IV. Task Force Conclusions

The limited applicability of the FHCDA maintains the status quo prior to its passage for hospice care outside of hospitals and nursing homes, which creates confusion and inequity. Without extending the authority bestowed by the FHCDA, would-be surrogates will continue to face the obstacles to decision making historically inherent in New York State, especially with respect to end-of-life care. Accordingly, the FHCDA should be amended to provide surrogates with authority to make health care decisions for hospice care outside of hospitals and nursing homes.

Promoting access to hospice, as well as supporting family participation in hospice care, is consistent with the intent of the legislature and overall regulatory approach to hospice care in New York State. The legislative declaration accompanying Article 40 of the Public Health Law, which governs hospice, states in pertinent part:

> In recognition of the value of hospice and consistent with state policy to encourage the expansion of health care service options available to New York state residents, it is the intention of the legislature that hospice be available to all who seek such care and that it becomes a permanent component of the state's health care system.[5]

Furthermore, the regulations governing hospice care envision family involvement and surrogate consent, stating, "if a patient is not capable of giving informed consent, written informed consent must be obtained from any individual who is legally authorized to give such consent on behalf of the patient."[6] The regulations also regard the patient and family as a unit, repeatedly referring to the "patient/family" when describing patient rights, the plan of care, and recordkeeping.[7] Extending the surrogate authority in the FHCDA to hospice care outside hospitals and nursing homes will help to ensure consistency in the application of associated laws and regulations.

The addition of hospice also fits well into the structure of the FHCDA as it currently stands, without requiring extensive changes. Hospices are federally certified and highly regulated at the state level. The safeguards and oversight mechanisms in the FHCDA, including the procedures for determining capacity, the procedures for end-of-life decision making, and the requirements of ethics review committees will translate into hospice settings. Hospices have physicians and other interdisciplinary professionals on staff to fulfill the statutory requirements in these areas, and most hospices have their own ethics committee, or have access to an ethics committee (*e.g.*, through an affiliated institution or other agreement).

V. Recommendations

Because the needs of hospice-eligible patients are immediate and compelling, and because hospice programs are regulated and structured in ways that generally would allow application of the FHCDA's standards and procedures, the Task Force recommends that the FHCDA should be amended to:

- Allow patients who meet the criteria for hospice, but cannot make decisions on their own, the ability to have a surrogate appointed for them pursuant to the FHCDA for decisions relating to hospice care.
  - When patients have no surrogate reasonably available, willing or competent, decisions should be made on a patient's behalf in accordance with standards and mechanisms already set forth in the FHCDA.[8]
- Apply similar presumptions and procedures currently in the FHCDA to the determination of whether a potential hospice patient lacks capacity, and to the selection of the individual who will serve as surrogate.
- Enable surrogates to elect hospice care on behalf of patients, regardless of where the patients reside at the time of the election.
- Authorize surrogate decision making for all care while in hospice, including creation of the hospice plan of care and decisions to withholding and withdrawing life-sustaining treatment, using similar standards for decision making and oversight mechanisms that the FHCDA currently requires in hospital and nursing home settings.

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Executive Director

On Behalf of the New York State
Task Force on Life and the Law

Endnotes

1. N.Y. Pub. Health Law Art. 29-CC § 1 (2010); *see also* N.Y. Pub. Health Law § 2994-b (applicability). More specifically, the FHCDA applies only to decisions regarding care provided in "hospitals," which is defined to include "general hospitals" and "residential health care facilities." *Id*. § 2994-a (18). A "residential health care facility" is "a nursing home or a facility providing health-related service." *Id.* § 2801 (3). Hereinafter, the terms "nursing home" and "residential health care facility" will be used interchangeably, and "general hospital" will be referred to as "hospital."
2. 2010 N.Y. Laws Ch. 8, § 28 (2).
3. The original Task Force proposal envisioned that surrogate authority would extend to all treatment decisions, without regard to where they were made, so long as appropriate safeguards were in place. However, the delivery of health care has changed significantly since the proposal was developed and it is prudent to reevaluate the effectiveness of the safeguards outside of the institutional settings of hospitals and nursing homes.
4. 42 C.F.R. § 418.24 (a) (2010); *see also* N. Y. Comp. Codes R. & Regs. tit. 10, § 793.6 (3) (2010).
5. N.Y. Pub. Health Law § 4000.
6. N.Y. Comp. Codes R. & Regs. tit. 10, § 793.6 (3).
7. *See*, *e.g.*, *id*. §§ 794.1-4.
8. Patients who do not have an individual available to act as a surrogate similarly stand to benefit from hospice care as their counterparts with surrogates, and therefore should have equal access to such care. While there are legitimate concerns about the vulnerability of these individuals, the safeguards required by the FHCDA, such as oversight by an Ethics Review Committee, will ensure that only patients who are eligible—and for whom such care is in their best interests—will have decisions regarding hospice care made on their behalf.

Extending the Family Health Care Decisions Act to Home Care

By Alfredo D. Cardillo, M.S.W.

This article reviews some of the issues that would need to be considered in a potential extension of the Family Health Care Decisions Act (FHCDA) to the home care setting. To properly appreciate these issues and indeed the larger context of surrogate health care decision making in the home care setting, the article provides an overview of home care in the evolving health care system, a review of New York's home care infrastructure, compelling reasons why FHCDA should be made applicable to home care, issues to consider in a potential extension, and options for bringing the FHCDA home.

Overview—Home Care and the Evolving Health Care System

The health care system is becoming increasingly integrated, encouraged by advancement in clinical practice, innovations in care management and technology, outcome/value based imperatives, incentives for efficiency, buy-in to integration by providers and payors, and progressive governmental policies.

In this context in which traditional modalities of care are being reexamined and opened to change, home health care has assumed an ever-deepening role in the delivery and coverage of care.

Home health agencies serve the gamut of patients, from new mothers and their infants to individuals over 100 years old, providing the range of preventive, pre-acute, post-acute, therapeutic, high-tech and chronic care. For a growing number of patients, home care is a core and collaborating component of their "medical home"—that "place" to which patients turn for their basic medical management needs and to which government and payors are further turning to bring the elements of the system together in a patient-centered, customized manner of care.

Home care has evolved to where it now flows to and between all of the various parts of the system; it is vitally connected to and with all levels of care. It is a prehospital intervention and a preventer of trips to the emergency room. In some models it is being directly substituted for acute inpatient stays. It has taken the place of the far end of hospital episodes, shifting this care to the home. It is the preferred setting for patient rehabilitation, and the choice for long term care over institutionalization.

The Home Care Infrastructure in New York State

The principal infrastructure of the New York's comprehensive home care system consists of Certified Home Health Agencies, Long Term Home Health Care Programs and Licensed Home Care Services Agencies.

Certified Home Health Agencies (CHHAs) are certified by the state under article thirty-six of the public health law to provide nursing, therapeutic and home health aide services under the Medicare and Medicaid programs.[1] CHHAs must meet the federal Medicare Conditions of Participation[2] along with an array of additional New York State regulations[3] for operation of their services, management of the patient's care and quality assurance. CHHAs may be free-standing agencies—such as a Visiting Nurse Association—or may be sponsored by hospitals, nursing homes or county/municipal health departments. CHHAs are responsible for developing, managing and providing the plan of care for an individual in his or her home. CHHAs cover a wide range of patients, and often provide the short-term skilled and rehabilitation services needed following hospitalization. CHHAs have many roles in the delivery of services in the community, ranging from preventive, public health and therapeutic services, to the management of chronic disease, to the care of individuals at the end of life. CHHA services are available statewide.

Long Term Home Health Care Programs (LTHHCPs), often referred to as the "Nursing Home Without Walls Program," are also agencies certified to participate in Medicaid and Medicare, but are specialized in the care of individuals who are otherwise medically eligible for admission to a nursing home.[4] LTHHCPs are sponsored by hospitals, nursing homes and CHHAs which receive specific state certification to provide a Long Term Home Health Care Program. LTHHCPs provide, coordinate and are responsible for managing a comprehensive plan of care for medically fragile adults and children, individuals with chronic illness and persons with disabilities. LTHHCPs are authorized to provide an extensive range of diverse and interdisciplinary services similar to the health, social and environmental supports provided in a nursing home. LTHHCPs must also meet the federal Conditions of Participation[5] as well as the array of state regulatory requirements[6] for operation, care management and quality assurance. LTHHCP services are available throughout the state,

except in a few of the most rural counties, where development continues to be explored.

Licensed home care services agencies (LHCSAs) are licensed by the state to provide paraprofessional and nursing services, often as subcontractors in the delivery of CHHA or LTHHCP services.[7] LHCSAs are not direct participants in Medicaid or Medicare, but subcontract with CHHAs, LTHHCPs or county departments of social services to provide services paid for by governmental plans. Under these subcontract arrangements, responsibility for the patient, the services and the plan of care rests with the CHHA and the LTHHCP. Like CHHAs and LTHHCPs, LHCSAs may also provide care to patients on a private pay basis or as covered by insurance or other third-party plans.

More and More Decisions Applicable to and Made Within the Home Setting

With the expanding role of home care and increasing integration of the system, more and more patient health encounters will be occurring in the home setting. Hence, more and more will a person's health care decisions be applicable to, and made within, the home.

As an example, emerging technologies are increasingly permitting through CHHAs and LTHHCPs daily monitoring and treatment decisions/interventions for patients with unstable or high risk conditions. Home telehealth allows for the daily monitoring of patient vital signs and other key health indicators, permitting diagnosis, decision making and intervention for patients without ever leaving the home. Thus is the case for patients suffering congestive heart failure, the most frequent cause of repeat hospitalizations. Increasingly, congestive heart failure patients can avoid hospitalization and emergency room use by being monitored at home by a home care agency. Among other vitals, agency staff are able to monitor the principal indicator of weight-gain (revealing likelihood of fluid retention) and address any necessary intervention with the patient and/or the patient's family and the physician, all in a diagnosis and decision making process without dislocation from the home.

Even apart from the growth and change in the field, all patients and providers in home health must routinely make decisions with regard to care and treatment for an infinite array of needs and circumstances; and, many patients, especially those in an advanced, medically fragile state, face highly critical decisions. As home care increasingly becomes a venue for individuals with advanced or potentially life-threatening conditions, it is increasingly the venue in which such decisions are faced.

Need to Extend the Family Health Care Decisions Act to the Home Setting

Although critical health care decision making is necessary in the home, state laws do not currently provide in home settings the same, clear structure recently provided for such decision making in hospitals and nursing homes when a patient loses health decision making capacity and no proxy or other legally authorized representative is available.

From the time that the Family Health Care Decisions Act was first introduced, in the early 1990s, until near to its final version in 2010, the proposed law applied to decisions made in virtually all health care settings. However, the complex and volatile concerns associated with the assignment of a surrogate decision maker which took the Legislature the better part of two decades to resolve, led the Legislature in its final agreement to start with a narrower law that applied only in hospital and nursing home settings.

While this approach helped secure an agreement on the law and provided a secure starting point for implementation, the Legislature recognized the necessity to right away begin work toward researching the extension of the FHCDA to additional settings.

With new procedures and clarity for hospitals and nursing homes, the new law simultaneously creates a cliff in applicability to other settings, like home care. Under the FHCDA, in order for surrogates to be appointed and/or for decisions to be made for patients at home, home care patients have to be hospitalized or placed in a nursing home, or the home care provider or family must seek "workarounds" and be faced with inconsistency of procedure, such as what existed for hospitals and nursing homes prior to the FHCDA.

Case in point #1: Patient "A" suffers from dementia. While hospitalized, the patient is determined to have lost capacity for health care decision making. The patient's spouse is appointed surrogate during the hospitalization. The patient is then discharged home. A home care plan is instituted to provide care for the patient. The dementia progresses and the patient loses the ability to swallow and is at risk of aspiration, pneumonia and possible death. Under the existing FHCDA, the surrogate cannot make a decision to forgo medical treatment for this life-threatening condition for this patient while the patient is at home—because the FHCDA is not applicable to the home setting. In order for or the surrogate to be able to make this decision, the patient would have to be hospitalized or admitted to a nursing home, where the decision to forgo treatment

would be made and the patient subsequently returned home.

Case in point #2: A diabetic patient with severely and rapidly deteriorating health, and without a surrogate, is determined to have a gangrenous leg, which without treatment/amputation will hasten death. Various members of the patient's family claim that the individual, if able to make his or her own decision, would never choose the amputation and would prefer to pass without this additional suffering. Under the FHCDA, neither the appointment of one of the family members to be surrogate, nor the decision to forgo amputation, could be made in the home environment. For these decisions to be made, the current law would require the patient to be hospitalized for the appointment of a surrogate and for the surrogate to decide on behalf of the patient to forgo the treatment and return the patient home.

Case in point #3: Assume the same diabetic patient in Case #2, but this time the patient's physician is offering, as an alternative to amputation, a powerful medication with possible serious side effects, to be administered by IV at home. The closest family wants to consent to the treatment on behalf of the patient, but the physician questions the family member's authority to decide. Here again, for the family member to have clear authority to decide, it would appear necessary to hospitalize the patient, whereupon the family member would become an FHCDA surrogate.

The lack of the extension of the FHCDA to the home setting and the consequences as described above are improper for both the patient and the system.

Issues to Address in Extending the FHCDA to the Home

In implementing the Legislature's directive to explore the extension of the FHCDA to other settings,[8] in fall 2010 the New York State Task Force on Life and Law reached out to the Home Care Association of New York State (HCA) to engage the Association in researching home care. To facilitate this research, HCA convened a workgroup of home care clinicians and administrators to review the provisions of the FHCDA and, considering the parameters, protections and other provisions of that law, identify what issues would have to be addressed to feasibly and properly extend the law to home care. Several of these issues are next discussed in this section.

1. What Should Constitute "Home Care" for Purposes of FHCDA Extension to the Home?

In extending the FHCDA to home care, it will have to be determined whether "home care" should mean only the general setting in which the patient resides or, more specifically, a patient at home under the care of a formal home care program (a CHHA or LTHHCP).

As the FHCDA is currently constructed, the patient's "care setting"—i.e., a general hospital or nursing home—functions as the patient's principal health care provider, through which the FHCDA's procedural and quality assurance mechanisms are established and ensured for the patient.

Thus, if the Act were to be extended to patients at home, the closet parallel to the existing FHCDA would be to extend its provisions through the patient's principal provider in the home setting, and thus to patients at home under the care of a CHHA or LTHHCP. In this scenario, the FHCDA would ostensibly provide that CHHAs and LTHHCPs, in conjunction with the patient's physician, ensure for patients the same (or appropriately modified for the home) types of protections as the FHCDA requires of hospitals and nursing homes, including clinical determinations, ethics reviews and decision-making standards.

In the case of patients cared for at home by family or others but without connection to the formal home care system, the FHCDA's protections and protocols, which revolve around the participating provider and provider setting, would need a connection to some other provider base. Without a link to formal home care, this may be a quandary for the FHCDA and these patients. One suggestion may be that, unless there is an interest or plan for a such a patient to engage with a home care agency, the FHCDA provider connection may be most practically established with the patient's primary physician. Thus, a possible route for FHCDA coverage of such patients living at home, but not in home care, may be through eventual FHCDA extension to physician offices and the categorization of these patients as "under the care of a physician's office" instead of as "home care" patients.

2. The Home Environment Versus an Institutional Setting

An important issue in considering and navigating the FHCDA's extension to home care is the varied, personalized and comparatively dynamic nature of the home environment—vastly distinct from the institutional care settings in which the Act currently applies and operates.

Hospitals and nursing homes are a relatively tightly controlled environment, whereas the home is an open and personal setting, ultimately shaped by the patient and other household members.

In institutional environments, the clinical staff is present 'round the clock, including physician access. The total environment is under the purview of the facility's administration and the facility is subject to an array of regulatory standards.

The very essence of home care is that service is provided in the personalized environment of the patient's home.

In home care, the patient and/or family determine the environment, which is filled with autonomous personal and critical health choices. Professional assistance (i.e., contact with agency staff) is available 'round-the-clock in CHHAs and LTHHCPs; however, except in very limited cases, patients in home care are not accompanied by twenty-four hour on-site staff, as they are in institutions.

Patient care in an institution is provided in a provider-driven and controlled environment. Home care is the opposite; it is patient-driven and patient/family controlled. Within this characteristic of home care also lies the essence of the comfort and desire of individuals to receive health care at home, and for those at the end of life, makes it their vastly preferred place to live out their final days.

It is important, therefore, that the would-be operation of the FHCDA in home care be duly considerate of such distinguishing factors from institutional care. At a minimum, the extension of the Act should contemplate the relevant considerations and adaptations—from the law's current institutional focus—to make it compatible with and properly accommodating for both home care patients and providers.

3. FHCDA Key Features Will Require Adaptation for Home Care

Certain features which are fundamental to the FHCDA in its current institutional settings are not mandated for, and may not be present in the same way, in home care. In this regard, extension of the FHCDA to home care would require a thorough examination of these features and their capacity to be provided for or properly adapted for the home care field.

Attending Physician: The presence of and access to physicians and medical directors in hospitals and nursing homes, which are pivotal requirements in the current FHCDA, differ in the world of home care.

In institutions, "attending physicians" have primary responsibility for the care and treatment of patients. Attendings are responsible for the orders and on-site care of the patient.

Home care's "equivalent" of an attending physician is the "ordering physician." In home care, this physician issues the orders for the plan of care which is then implemented and managed by the home care provider. All home care is provided pursuant to physician orders. In home care, a physician orders the start of care, and these orders must be renewed at least every sixty days. The physician must otherwise approve changes in the plan of care.

Continuity with physicians can be challenging for Medicaid patients and hospital dischargees, whose orders for home care may be issued by a hospitalist and then shifted to a physician in the community, who for some Medicaid patients may be a physician in a clinic group. This dynamic, which is in contrast to the institutional sectors, must be acknowledged in designating or translating the "attending physician's" responsibilities in a potential FHCDA extension to home care.

Another area of variance in applying the current FHCDA to home care involves the FHCDA's specification of various roles for a Medical Director. Home care agencies are not required to have Medical Directors. However, some home care agencies have contractual or other organizational relationships with physicians, including the Medical Directors of the agency's parent sponsor if it is a hospital- or nursing home-based home care agency. In these cases, either the parent facility's Medical Director or other affiliated physician could perhaps serve in the prescribed roles required by the FHCDA, and indeed would need to be retained for such if the FHCDA were to be eventually extended to home care.

Ethics Committees: Unlike institutions under the FHCDA, home care agencies are not required to have the FHCDA's prescribed Ethics Committees. However, some home care providers either already have their own Ethics Committees or utilize the Ethics Committee of their parent hospital or nursing home if part of the same system.

Convening Ethics Committees would be a new mandate for home care agencies if the FHCDA were to be extended to home care. While a potentially good practice to have such committees in home care regardless of the FHCDA, requiring home care Ethics Committees at this time in an already well-overburdened field necessitates careful consideration. The issue of mandates in home care will be further discussed later in this article.

4. Determinations of Capacity/Incapacity

Under the FHCDA, determinations of incapacity are made by the attending physician; in nursing homes there must be an independent determination of incapacity by a health or social services practitioner employed by or otherwise formally affiliated with the facility.

In an FHCDA extension to home care, it is contemplated that determinations of incapacity could be made by the *ordering* physician (the physician who has ordered the home care plan of care) or by the patient's primary physician if other than the ordering physician. Recently implemented federal requirements for home care patient "face-to-face" encounters with physicians may facilitate such determinations, especially in start-of-care situations. As is the case in nursing homes, the added FHCDA protection of securing concurring opinions by a health or social services practitioner could be provided in the same way by the staff of the CHHA or LTHHCP.

5. Health Care Decisions for Patients Without Surrogates

The FHCDA establishes a framework for making routine medical decisions, major medical decisions and decisions to withhold or withdraw of life-sustaining treatment for patients *without* surrogates.

In home care, routine and major medical decisions need to be able to be made in a timely manner in the context of the patient's care and the home care agency's general operations. The current FHCDA authorizes a hospital or nursing home patient's attending physician to decide about routine medical treatment, and nothing in the Act requires health care providers to obtain specific consent for treatment where specific consent is not otherwise required by law.

It is contemplated that a parallel provision for home care could authorize the ordering physician in conjunction with the home care provider to be the sources for routine medical decisions.

Under the FHCDA, making a major medical treatment decision (such as the use of psychoactive medications, physical restraints, invasion of bodily integrity requiring incision, producing substantial pain, discomfort, debilitation or having a significant recovery period) requires the attending physician and a concurring opinion of at least one other designated physician, or Medical Director if the patient is in a nursing home. A health or social services practitioner may provide the concurring opinion if the decision is about the use of physical restraints.

If a parallel provision were to be established for home care, it is contemplated that the ordering physician could make the medical decision. However, in providing for the concurring opinion of a Medical Director (or other physician), the previously discussed issue that home care providers do not currently routinely have a Medical Director would need to be addressed. While many of the major medical decisions that meet the criteria of the FHCDA would be more apt to be applicable in a hospital than in a patient's home, as the system evolves and more and more complex care is provided in the home, more and more of these treatment decisions will likewise be made in the home.

Under FHCDA, decisions to withhold or withdraw life-sustaining treatment would require either a court of competent jurisdiction or a decision by the attending physician, with independent concurrence of a second physician designated by the hospital or nursing home, that to a reasonable degree of medical certainty (i) life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the provision of life-sustaining treatment would violate accepted medical standards.

If the FHCDA were to be extended to home care, it is contemplated that the same process and protections would be required of the provider and accorded the patient.

6. New Mandates

Home care agencies are currently besieged by new and mounting state and federal mandates. HCA has estimated that in just past several years, these mandates have resulted in $75 million in unfunded obligations. Moreover, the state and federal budget processes have unleashed unprecedented cuts to the health care system, home care included. New requirements which might be imposed on home care agencies as a result of a possible FHCDA extension must be carefully and thoughtfully evaluated in this context.

Potential Options for FHCDA Extension to Home Care

Considering the aforementioned issues, one suggested option for allowing FHCDA extension to home care is to provide legislative authority for a provider opt-in process, beginning with CHHAs and LTHHCPs. While an opt-in would not bring FHCDA authority to initially nonparticipating providers, it would indeed allow for a tested and gradual period of FHCDA implementation in home care through the participating agencies, with issues able to be identified and addressed on the front end. Given the important and fundamental goal at stake for the patients, as well as the integrity of the health care decision making process outside of the institutional sector, such a proposed opt-in merits serious consideration.

Indeed, "home is where the heart is." Home is where people in need of care overwhelmingly prefer to be and the direction in which health care continues to move. Our laws, rules and opportunities should similarly follow that course.

Endnotes

1. NY Public Health Law §§3606, 3608.
2. 42 CFR Part 484.
3. 10 NYCRR Part 761.
4. NY Public Health Law §§3610, 3616.
5. 42 CFR Part 484.
6. 10 NYCRR Part 761.
7. NY Public Health Law §3605; 10 NYCRR Part 766.
8. NY Laws of 2010, Ch. 8, §28.2.

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Ethics Committees Under the Family Health Care Decisions Act: From Policy to Practice

By Tracy E. Miller

On June 1, 2010, the Family Health Care Decisions Act (the "FHCDA" or the "Act") became effective in New York State.[1] First proposed by the New York State Task Force on Life and the Law in 1992, the Act effects sweeping changes to New York State's laws on treatment decisions for patients in hospitals and nursing homes.[2] Specifically, the FHCDA establishes a new Article 29-CC of the Public Health Law that covers treatment decisions, including decisions to forgo life-sustaining measures, for adults who lack the capacity to decide for themselves and have not signed an advance directive, and for children.

With passage of the FHCDA, New York became one of the first states in the nation to mandate that hospitals and nursing homes establish or participate in an ethics committee ("Ethics Committee") with a significant role in resolving disputes, providing ethics advice, and authorizing decisions by family members or other surrogates to withdraw or withhold life-sustaining treatment. In contrast to many state laws on surrogate decisions that do not permit surrogates to forgo life-sustaining treatment for patients who lack capacity and are neither terminally ill nor permanently unconscious, New York State did not preclude surrogates from making decisions in certain cases or require judicial approval. As explained by the Task Force on Life and the Law in proposing the FHCDA:

> Looking at the two poles of decision-making models for in-capacitated patients—the medical model of informal decisions at the bedside and the judicial model with all its procedural and evidentiary requirements—the Task Force has carved a middle path between the two. In doing so, it seeks to balance the need to protect patients from poor decisions with the need for policies that work in the context of medical practice.[3]

Hence, rather than arbitrarily limit surrogate authority, the Task Force proposed reliance on Ethics Committees as a safeguard for decisions in sensitive cases. As a result, Ethics Committees in New York State now have significant new authority as well as corresponding duties under the FHCDA. This article briefly describes the decision-making process established by the FHCDA and then discusses the role of Ethics Committees under the FHCDA, requirements for committee membership, procedures for the committees, and practical approaches to fulfilling the committees' obligations.

I. Decision Making Under the Family Health Care Decisions Act

The FHCDA replaces long-standing case law in New York State that severely limited the authority of family members and others close to the patient to withdraw or withhold life-sustaining measures, in the absence of a health care proxy or living will.[4] In particular, the FHCDA eliminated "clear and convincing evidence" of an adult's wishes about treatment as the sole basis for decisions to forgo life-sustaining treatment once patients lose decision-making capacity and have not signed a health care proxy. For adult patients who do not have the capacity to decide for themselves and have not executed an advance directive, the FHCDA authorizes family members and others close to the patient to decide about treatment, including life-sustaining measures.

The FHCDA specifies the following priority list of individuals who can decide about treatment for patients determined to lack decision-making capacity: (i) a guardian authorized to make health care decisions pursuant to Article 81 of the Mental Hygiene Law; (ii) the spouse, if not legally separated from the patient, or the domestic partner; (iii) a son or daughter 18 years of age or older; (iv) a parent; (v) a brother or sister 18 years of age or older; or (vi) a close friend.[5] An individual from the highest priority class on the list who is reasonably available, willing, and competent to decide, will be authorized as a "surrogate" for treatment decisions.

The FHCDA grants surrogates the authority to make all health care decisions that an adult patient could make, as long as the decision satisfies the standards under the Act. Surrogates must decide about treatment in accord with the patient's wishes, including religious and moral beliefs, to the extent they are reasonably known, or, if they are not known, in accord with the patient's best interests.[6] In addition to meeting those standards, surrogates can decide to forgo life-sustaining measures if: (i) treatment is an extraordinary burden and the patient is terminally ill or permanently unconscious, or (ii) the patient has an incurable or irreversible condition and the treatment would entail such pain, suffering or other burden that it would reasonably be deemed inhumane or excessively burdensome under the circumstances. As discuss below, Ethics Committee review and approval is also required in certain cases.

In addition to decisions for adults, the FHCDA covers decisions to forgo life-sustaining treatment for children.[7]

The FHCDA authorizes parents of minor children to forgo life-sustaining measures in accord with the Act's standards, resolving the uncertainty that has long marked parental authority for such decisions under New York State case law.[8] The Act also establishes that emancipated minors, if determined to have the capacity to decide about treatment, are authorized to consent to forgo life-sustaining treatment, if the attending physician and the Ethics Committee determine that the decision accords with the standards in the Act for such decisions.[9]

II. Ethics Committees

The FHCDA requires all hospitals and nursing homes to establish an Ethics Committee or participate in an Ethics Committee that serves more than one facility.[10] The Act also assigns significant responsibilities to Ethics Committees, and mandates that they satisfy certain requirements for membership, notice to patients and surrogates, procedures for meetings, and confidentiality. Notably, the Act grants protection from civil and criminal liability as well as charges of professional misconduct to health care facilities and Ethics Committee members, participants and consultants for actions taken reasonably and in good faith pursuant to the Act.

A. Role and Responsibilities

The Act specifies that Ethics Committees will: (i) consider and respond to any health care matter or request for assistance in resolving a dispute presented by the patient, surrogate, or other persons identified in the Act; and (ii) review certain sensitive decisions by surrogates and mature minors. Ethics Committees have an obligation to respond promptly to a request for assistance or dispute resolution by a "Person Connected with the Case," defined in the Act to include the patient, any member of the surrogate list, an attending physician, any other health or social service practitioner directly involved in the patient's care, and any duly authorized state agency, including the facility director or regional director for a patient transferred from a mental hygiene or correctional facility. This provision, as with others throughout the Act, recognizes the important role played by nurses, social workers, and other professionals at the bedside who are not physicians. These professionals may have clinical knowledge, insight about the patient's personal wishes and circumstances, and a professional commitment to the patient's well-being that may be important in bringing concerns to the attention of the Ethics Committee. This is especially true in long-term care facilities where nurses and social workers are often the primary caregivers, with significant interaction with the patient and family members.

A request for assistance to the Ethics Committee or a dispute brought to the Committee's attention may arise for various reasons, including: (i) disagreement among members of the surrogate list about a treatment decision; (ii) disagreement between a surrogate and the attending physician or other staff member about a treatment decision; (iii) disagreement about the determination of the patient's decision-making capacity; or (iv) conflict or uncertainty about whether the patient meets the standards for decisions to forgo life-sustaining treatment under the Act. This is not an exclusive list of matters that Ethics Committees may address; the committees have a broad mandate under the FHCDA to consider matters brought to them.

In cases where an Ethics Committee responds to requests for assistance or dispute resolution, an Ethics Committee can provide advice about the ethical aspects of proposed health care, make a recommendation, or seek to resolve a dispute. Ethics Committees have significant latitude to determine how best to carry out this responsibility; for example, depending on the nature of the issue or dispute, an Ethics Committee could recommend an ethics or social work consultation, or seek another opinion about the patient's capacity or prognosis. Indeed, fact-finding in relation to the patient's diagnosis and prognosis as well as non-medical factors, such as the patient's wishes, may be a common role for Ethics Committees. Conflict at the bedside often arises due to poor communication by health care professionals, lack of understanding about the patient's diagnosis or prognosis, or misunderstanding among family members.

Ethics Committees have the most substantial responsibility in cases where their decisions are binding. This responsibility arises for decisions to forgo life-sustaining treatment in the following cases: (i) in a hospital, for decisions to forgo artificial nutrition and hydration for a patient who is not terminally ill or permanently unconscious, if a physician disagrees with the surrogate's decision; (ii) in a long-term care facility, if a surrogate consents to withdraw or withhold life-sustaining treatment for a patient who is not terminally ill or permanently unconscious, except that Ethics Committee review and approval is not required for decisions to forgo cardiopulmonary resuscitation for such a patient; and (iii) in a hospital or long-term care facility, if an emancipated minor consents to withdraw or withhold life-sustaining treatment.

In these cases, the FHCDA charges Ethics Committees to review the decision to forgo life-sustaining treatment by a family member, other surrogate or a mature minor, and determine if the decision meets the standards under the Act. Notably, Ethics Committee decisions in these cases are binding, unless a court order overrides the Ethic Committee's decision. It is significant as well that, in these cases, Ethics Committees are charged to determine whether the decision-making standards in the law have been met, not to make a *de novo* decision for the patient, with the exception of decisions regarding emancipated minors. Admittedly, the best interests standard in the law leaves ample room for judgment, calling for a decision that takes into account factors such as consideration of the dignity of every person, the possibility and extent of preserving the patient's life, the

preservation or restoration of functioning, and the relief of suffering.[11] However, Ethics Committees should recognize that they are not authorized to act as the surrogate, but as a check on a surrogate decision that is not consistent with the patient-centered standards in the Act. As noted above, decisions for emancipated minors are an exception. In those cases, the Act seeks to address the vulnerability of some emancipated minors by conditioning the minor's authority to make the decision on: (i) an Ethics Committee determination that the decision accords with standards for the decision on behalf of adults, and (ii) approval by the Ethics Committee.[12]

Prior to passage of the FHCDA, Ethics Committees fulfilled a variety of functions within facilities, including education, policy setting, and discussion. Facilities can assign these and other duties to the Ethics Committee, or convene a subcommittee to perform these functions. Facilities with a large well-established Ethics Committee may wish to create a subcommittee to fulfill duties under the FHCDA consistent with requirements under the Act. Under this approach, it would be a useful procedure if the subcommittee reports its decisions and actions to the full Ethics Committee for retrospective analysis.

B. Ethics Committee Membership

As required by the FHCDA, the membership of the Ethics Committee must be interdisciplinary and must include at least five members who have demonstrated an interest in or commitment to patient's rights or to the medical, public health, or social needs of those who are ill. The members may include health care professionals, clergy, and others employed or affiliated with the hospital or nursing home, as well as members of the community. At least three Ethics Committee members must be health or social service practitioners, at least one of whom must be a physician, and at least one of whom must be a registered nurse. In addition, at least one Ethics Committee member must be a person without any governance, employment, or contractual relationship with the hospital or nursing home. A Person Connected with the Case may not participate as an Ethics Committee member in considering that case.

Additional requirements apply in long-term care facilities. Nursing homes must offer the Residents' Council of the facility, or of another facility that participates in the Ethics Committee, the opportunity to appoint up to two persons to the Committee, neither of whom may be a resident of or a family member of a resident of the facility. Both must have expertise in or a demonstrated commitment to patients through professional or community activities, other than activities performed as a health care provider.

Ethics Committees should seek to assure that committee membership accords access to the expertise and leadership needed. Among other matters, Ethics Committees should give careful consideration as to whether an attorney should serve as a member of or a regular participant in Ethics Committee meetings. Attorneys can provide valuable insight about the law, but their role should be clarified. Counsel should see their role as identifying the range of treatment decisions or options supported by the FHCDA and the facts, rather than as identifying the "safest" course of action for the facility, a role that may conflict with the patient's wishes or interests.[13] Moreover, the FHCDA includes a provision establishing that a facility or physician that provides treatment or services refused by a surrogate acting in accord with standards under the FHCDA is not entitled to payment for such treatment or services.[14] Hence, the course seen as "safest" can prove costly for the facility if it is not well-grounded in the Act's decision-making standards which focus exclusively on the patient's wishes and interests.

C. Ethics Committee Procedures

Ethics Committees must adopt a written policy governing committee functions, composition, and procedures that accords with FHCDA requirements. In addition, as with other institutional committees, bylaws or policies for Ethics Committees should set forth a process to appoint the members, appoint or choose a chairperson, provide notice of meetings, and establish a quorum for the meetings. As they carry out responsibilities under the FHCDA, Ethics Committees must follow the procedures specified in the Act. Ethics Committees must respond promptly, as required by the circumstances, to: (i) any request for assistance in resolving a dispute by a Person Connected with the Case, or (ii) a request for consideration of a surrogate decision to withdraw or withhold life-sustaining treatment in the cases identified above. Ethics Committees must also promptly give the patient (if there is any indication of the patient's ability to comprehend the information), the surrogate, other persons on the surrogate list directly involved in the decision or dispute regarding the patient's care, the attending physician, a designated representative of the facility's administration, and any other person the Ethics Committee deems appropriate the following:

(a) notice of any pending case consideration concerning the patient, and, for patients and persons on the surrogate list, information about the Ethics Committee's procedures, composition, and function; and

(b) the Ethics Committee's response to the case, including a written statement of the reasons for approving or disapproving a surrogate's decision to withdraw or withhold life-sustaining treatment for a patient who is not terminally ill or permanently unconscious, or for a decision by a mature minor to forgo life-sustaining treatment.

Persons Connected with the Case must have an opportunity to present their views to the Ethics Committee and also the option of being accompanied by an advisor when

participating in an Ethics Committee meeting. In some circumstances, patients or individuals on the surrogate list may choose not to participate in the Ethics Committee process. They should not be forced to do so. Instead, representatives of the Ethics Committee or the facility should still explain the process to them and solicit their views, concerns, and any information they can provide about relevant aspects of the case, including insight about the patient's wishes and values, or, if not known, a judgment about the patient's best interests.

An Ethics Committee may establish policies or procedures to seek to resolve any disputes that arise by less formal means before referring the matter to the Ethics Committee, including, but not limited to, an ethics, social work, or other consultation. For patients or individuals on the surrogate list intimidated by the process, this more informal consultation may be preferable.

The Ethics Committee's response to each case covered in which its decisions are binding must be in writing and included in the patient's medical record. While Ethics Committee proceedings and records are generally confidential and not subject to disclosure, the New York State Department of Health may review the written decisions of Ethics Committees, as well as records of the proceedings, in cases where the decision is binding. Ethics Committees should therefore consider carefully the form that their written decisions will take and how they will be communicated to family members and other surrogates when the Ethics Committee's decision is binding. Ethics Committees should also develop clear policies and procedures regarding minutes of the meetings and other Ethics Committee records.

III. Conclusion

The FHCDA grants substantial authority to Ethics Committees as a vehicle to resolve disputes, to provide advice to health care professionals, family members and others close to the patient, and to serve as a safeguard for certain sensitive decisions to forgo life-sustaining treatment. Without question, the Act presents challenges to Ethics Committees, especially those in smaller institutions that lack a strong history of ethics consultation or meetings.

Ethics Committees have a clear obligation to seek the training, expertise, and information they need. At a minimum, training should include broadly accepted ethical principles for treatment decisions, committee members' obligations and committee procedures, and the requirements of the FHCDA and other related laws such as the health care proxy law. Ethics Committee members should also recognize that the Ethics Committee is designed to serve the needs of patients and those close to them. The FHCDA as a whole, including the protection from liability for health care facilities and Ethics Committee members, participants and consultants who act reasonably and in good faith pursuant to the Act, seeks to remove legal obstacles in order to allow a decision-making process that places the patient's wishes and best interests at its center.

Endnotes

1. N.Y. Public Health Law, Article 29-CC (2010).
2. New York State Task Force on Life and the Law, *When Others Must Choose; Deciding for Patients without Capacity* (March 1992). The FHCDA was first introduced in the Legislature in March 1993. *See* A.7166.
3. New York State Task Force on Life and the Law, p. 76.
4. *In re Storar*, 52 N.Y.2d 363 (1981), *cert. denied*, 454 U.S. 858 (1981); *In re Westchester County Medical Center*, 72 N.Y.2d 517 (1988).
5. N.Y. Public Health Law § 2994-d. Recognizing the continuing importance of New York's health care proxy law, and the preference given to individuals appointed by adults to decide about treatment for them, the FHCDA specifies that if an adult has executed a health care proxy, the person appointed takes priority over those authorized by the FHCDA to make decisions. Decisions by a health care agent are governed by New York's Health Care Proxy Law. *See* N.Y. Public Health Law, Article 29-C.
6. For decision-making standards under the FHCDA, *see* § 2994-d(4).
7. N.Y. Public Health Law § 2995-e.
8. *See* In re Storar 52 N.Y.2d at 363.
9. N.Y. Public Health Law § 2994-e(3).
10. *See* N.Y. Public Health Law § 2994-m for provisions that govern Ethics Committee procedures, membership and responsibilities.
11. N.Y. Public Health Law § 2994-d(4).
12. N.Y. Public Health Law § 2994-e(3). As explained by the Task Force, "Particularly when considering decisions by homeless and runaway adolescents to forgo treatment, the review committee should help ensure that chronically or terminally ill minors do not refuse treatment and choose to die because they feel they have limited options for continuing their lives. Health care professionals should try to secure all available psychosocial support and encourage the minor to separate the despair that may accompany life on the streets from the burdens associated with the provision of life-sustaining treatment." New York State Task Force on Life and the Law, p. 134.
13. *See* New York State Task Force on Life and the Law, p. 144.
14. N.Y. Public Health Law § 2994-s.

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Educating Ethics Review Committees in a More Humanistic Approach to Relational Decision Making

By Mary Beth Morrissey

Introduction

As we approach the one-year anniversary of the effective date of the Family Health Care Decisions Act, landmark legislation in New York State, it has become increasingly clear to legal and health care practitioners, as well as policymakers, that there have been unforeseen challenges in implementing the law on the ground in clinical practice settings. Many of those challenges relate to ethical issues and ethical dilemmas in decision making for which there are no prescriptive formulae, such as negotiating sometimes complex relationships and conflicts within families, and between health care professionals and surrogates who are now legally authorized to act for incapable patients. A more humanistic approach to understanding relationships and conflicts deepens understanding of lived experiences of illness burden, pain and suffering for seriously ill patients and their family members, and the fully relational dimensions of the health care decision making process.

The architects of the Family Health Care Decisions Act wisely saw that it would be prudent to obligate all nursing homes and hospitals covered under the law to establish ethics review committees. While many health care facilities may already have such committees in place, the Family Health Care Decisions Act establishes an authoritative function of the ethics review committee, which I will address more fully below. However, what is essential to the proper functioning of the ethics review committees under the Family Health Care Decisions Act, particularly in view of their newly expanded responsibilities, is comprehensive education for committee members in a number of critical areas.

Importantly, there is growing research evidence that many health care professionals today lack adequate training in palliative and end-of-life care, both in the U.S. and outside the U.S. A recent report issued by the Lien Foundation ranking end-of-life care across the world puts the U.S. at 9th among 40 countries across the world based upon measures of quality and availability of end-of-life care.[1] The Lien Foundation white paper also addresses in more depth the continuum of sociological, cultural and ethical issues that affect end-of-life care. One of the key recommendations in the report is the centrality of capacity building and training to the growth of palliative care, not only for physicians, nurses and other health care professionals, but for community-based volunteers and caregivers.

Palliative care both as a philosophy of care and as a delivery system is a meaningful context for understanding the Family Health Care Decisions Act, its legislative goals and its implementation. Consistent with this context, it would be important to include content on the Palliative Care Information Act,[2] effective February 2011, and its implementation in educational curricula for ethics review committees.

My focus in this article is to provide a brief overview of the core areas for ethics review committee training in light of the requirements of the Family Health Care Decision Act and the Palliative Care Information Act in the larger context of palliative care, as well as the radically changing health care environment in which families, health care professionals and health care providers are navigating as they enter a new era of health care decision making.

Core Curricula Areas for Ethics Review Committee Education

There are several critical areas that should be included in a comprehensive educational curricula for ethics review committees under the Family Health Care Decisions Act (FHCDA) and the Palliative Care Information Act (PCIA), as summarized below:

- Introduce foundational content on the existing legal and ethical consensus for decision making, and the principles and goals of palliative care;
- Explain paradigm shift in health care decision making framework, relevance to interdisciplinary team process and communication skill competencies of team members;
- Describe the paradigm shift in functions of the ethics review committee as defined under the FHCDA, committee process and procedures specific to the facility ethics review committee, and responsibilities of ethics review committee members;
- Provide targeted overview of key provisions of the FHCDA and PCIA, including decision making standards, applicable facility policies on health care decision making, and implementation challenges;
- Discuss the role and responsibility of the ethics review committee in addressing conflict and assisting in resolving conflict;
- Formulate consensus about adoption of best practice to assure ethically competent functioning of the eth-

ics review committee, and consultation and communication with family members, surrogates, and health care professionals.

While it is not possible to address each of these areas exhaustively in this short article, I will touch upon the central purpose of the education in each core area. In developing or modifying an educational curricula to find the best "fit" for the particular facility and ethics review committee being trained, certain decisions will have to be considered in consultation with the leadership of the committee or the parties who have requested the training. One important decision is whether the training should be presented in one or two modules or sessions. This decision may depend on facility resources and availability of, or access to, committee members. The second decision is determining the time and resources that should be invested in developing written curricula for the training program. Certain parts of the written curricula may be standardized, but other parts may be facility-dependent. It is advised, however, that there be written curricula materials developed and provided to the ethics review committee members to supplement the training that will be presented to them based upon the core educational curricula.

A third decision is whether to include an interdisciplinary professional, or professionals from a mix of disciplines, in the training program. It is frequently very helpful to incorporate an interdisciplinary perspective and have representation from more than one discipline in conducting training programs, especially for a body such as an interdisciplinary ethics review committee.

Legal and Ethical Consensus; Principles and Goals of Palliative Care

The provisions of the FHCDA address the composition of ethics review committees.[3] Hospitals and nursing homes are required to have a written policy that has provisions addressing ethics review committee composition.[4] While the provisions of the FHCDA on composition impose certain prescriptive requirements on hospitals and nursing homes such as interdisciplinarity and number of health and social services practitioners,[5] covered institutions may still exercise certain discretion in terms of how they draft their policy provisions on committee membership, operationalize the applicable requirements, and form or restructure the membership of committees. For this reason, committee members will likely have very diverse backgrounds, knowledge and training in ethics and health care decision making.

It is critical that professionals who are developing educational curricula for ethics committee members not take for granted that all individual members of the committee have a working knowledge of essential constituents of the existing legal and ethical consensus about decision making under applicable federal and state laws and regulations, as well as broadly accepted consensus statements on ethical aspects of treatment decisions issued by national or state bodies such as statements on palliative sedation.[6] It is always helpful to have a sense of the knowledge level among the individuals being trained. Frequently, however, that will not be possible. The goal of introducing this content is to lay a foundation for the new information that will be provided in the training session about targeted provisions of the FHCDA and the PCIA, and the complexities arising under those laws with respect to ethical issues involving decision making.

In this introductory segment of the training, it is appropriate to define the objectives of the training and integrate the broad goals of palliative care with those objectives.

Participants in the training should be made aware of the PCIA, effective February 2011, and how its provisions and requirements intersect with the provisions of the FHCDA. Under the new law, attending practitioners are required to offer patients who are terminally ill (an illness or condition that can reasonably be expected to cause death within 6 months with or without treatment) information and counseling regarding palliative care and end-of-life options appropriate to the patient.[7] When the patient lacks decision-making capacity, the information and counseling must be offered to the person who has legal authority to make decisions for the patient.[8] Consistent with the work of Joseph J. Fins (2006), who framed the overarching heuristic of a palliative ethic of care,[9] it is imperative to spend time in the training session describing the principles and goals of palliative care in enhancing quality of life, relieving suffering, fostering effective communication and supporting patient-centered decision making. This education is critical to helping committee members understand the connections in palliative care between interdisciplinary team practice, communication and good decision making. This context will provide committee members with a heightened awareness and sensitivity to the limits of the medical futility principle in resolving conflicts at the bedside,[10] and foster a more humanistic attitude toward working with suffering family members and addressing their ethical concerns.[11] Committee members should be provided with literature on palliative care, or at a minimum references to resources that provide information about palliative care such as the National Consensus Project for Quality Palliative Care and the Center to Advance Palliative Care at the Mount Sinai School of Medicine, New York City.[12]

Following a discussion of the goals of palliative care, it would be important to review at least briefly certain key points of the existing legal and ethical consensus in the areas of advance care planning, resident/patient rights,

informed consent and decision making, refusal of treatment, life-sustaining treatment, withholding and withdrawal of life-sustaining treatment, pain and symptom management, and palliative sedation (including some of the defined terms under the statutes), in an effort to put everyone on the same page. As it is unlikely that time constraints will permit a comprehensive review of this information, written materials should be provided to the committee members in each of these areas referencing applicable law and applicable consensus statements of appropriate bodies.

Paradigm Shift: Relational Framework in Decision Making

In the years following the *Cruzan*[13] decision, and the enactment of the federal Patient Self-Determination Act of 1990[14] and the New York State Health Care Proxy Law,[15] policy making in the area of health care decision making has been driven in large part by the patient rights movement.[16] The legal and ethical underpinnings for such policy making have been based on well-established ethical principles of patient autonomy and health care justice. However, the rational choice, self-interested agency and transactional pillars of the individualistic framework have been challenged on a number of fronts as inadequate and not sufficiently accommodating cultural differences in decision making, social, ecological and community contexts, and the multidimensional aspects of person-centered decision making—psychological, cognitive, emotional, spiritual, axiological.[17] The movement away from a contractarian, formalistic approach and toward a more relational framework of decision making marks the next era in the ethics of health care decision making. This shift reflects the humanistic perspective that persons are fundamentally social and relational, and that rights are relational. It also challenges the widely held notion that health care decision making has only epistemological foundations.

The enactment of the FHCDA in New York is consistent with this paradigm shift. The statute formally recognizes in law the well-established social and ethical role and responsibilities of families and family members as relational others and in many cases, as caregivers, in the health care decision-making process. It is long overdue that this role be given legal status and legitimacy in our statutes, policies and systems of decision making. Ethics committee members need to be introduced to the relational framework in decision making and its essential constituents: the interpersonal relationship, communication that is founded on relationality, moral agency and responsibility, and collaborative practice. This education should be integrated into a description of the role of the interdisciplinary team in clinical settings, and the relevance of the paradigm to effective functioning of the interdisciplinary team at the specific facility.

The last component of the education in this core area that should be touched upon is to expose committee members to some understanding of the complexity of decision-making that is involved in any decision-making process across systems. Briefly, the levels of decision making that should be identified are the microsystem in which the patient and the patient's experiences and interactions with the patient's family members, surrogate and personal support systems are situated, facility policies and systems, and the macrosystem external to the facility that influences such aspects of decision making as determination of government benefits and allocation of resources. Health care decisions usually involve interaction and communication across all system levels. For example, a surrogate who is weighing a decision to withdraw or withhold life sustaining-treatment for a terminally patient will be offered information and counseling from the patient's attending practitioner about palliative and end of-life care options for the patient under the PCIA, such as referral to hospice and eligibility for the Medicare hospice benefit. There are multiple systems involved in the surrogate's decision-making process.

Paradigm Shift: Function of Ethics Review Committees

The FHCDA marks a paradigm shift not only in the role of families in decision making, but also in the role of ethics review committees in the decision-making process. The statute establishes an authoritative function of the ethics review committee by investing it with legal authority to make binding decisions on certain matters.[18] The traditional consultative role of the ethics review committee is formalized under the statute. The statutory provisions spell out that consistent with the functions of the ethics review committee, permitted responses to a matter it has reviewed may include advising, making a recommendation, or assisting in resolving a dispute about proposed health care.[19] More specifically, however, the ethics review committee mandate under the statute is that it shall consider and respond to any matter submitted to it by a person connected with the case.[20] This is a very broad mandate. The responsibility of ethics committee members to carry out this mandate has significant meaning for seriously ill patients, their family members and surrogates.

The recommendations and advice of the committee shall be advisory and non-binding, except when a mandated review of a surrogate decision to withhold or withdraw life-sustaining treatment is triggered.[21] In these cases, the determination of the committee to approve or disapprove the decision withholding or withdrawing life-sustaining treatment is binding.[22] This new authoritative function of ethics committees will require much more extensive training for ethics committee members to assure that they are properly qualified to carry out this weighty charge.

Explaining the complexity of decisions to forgo treatment, especially life-sustaining treatment, and the multilayered process of decision making involved in the choices and deliberations about treatments, risks, benefits and burdens, and alternative treatments, is a *sine qua non* of the training. Consistent with the relational paradigm of decision making, committee members will need to understand that their charge in reviewing surrogate decisions to withhold and withdraw life-sustaining treatment and issue a binding approval or disapproval of such decisions is a responsibility that puts them in ethical relation to the resident/patient and the surrogate and ought not be taken lightly.

With respect to ethics committee process and procedures, the provisions in the statute are skeletal. Facilities governed by the law need to have clearly delineated policies that address committee process and procedures. There is room for wide variation in terms of how the provisions of the statute can be operationalized. The training should cover the process and procedures of the specific facility policy as well as the statutory provisions, including respecting confidentiality of the committee process.

Members of the ethics committee should also be sensitized to the potential for conflicts of interest between professional codes of ethics for professionals in their respective disciplines represented on the committee, facility policies on health care decision making, or decisions made by the ethics review committee. This type of conflict is to be distinguished from conflicts of interest that arise due to a contractual relationship with the facility, or from conscience objections to treatment decisions made pursuant to the FHCDA. A decision on an ethical issue that presents a potential conflict for a social worker may not present a similar conflict for a physician or a nurse. The ethics of health care decision making and health care justice do not have a universal meaning for all professionals in all disciplines.

Targeted Review of FHCDA and PCIA: Decision-Making Standards and Patient Rights

The enactment of the FHCDA, while a positive and welcome step in New York, does add complexity to the health care decision-making process. In the larger framework of federal and state laws and regulations governing health care decision making, it is important to explain to ethics committee members how the law fits into the existing legal and regulatory scheme, as well as how it interacts with the PCIA. The focus of this review should be targeted to the scope of the law, surrogate selection, the legal authority of the surrogate, informed decision making and such areas of the statute that may give rise to conflict including capacity determinations, who is qualified under the statute and facility policy to make capacity determinations, and application of the clinical standards.

One of the most important areas of the training is the work that the training professionals will need to do with ethics committee members to enable them to understand the decision-making standards. Under the FHCDA, there are two sets of standards, broad patient-centered standards[23] and standards for life-sustaining treatment decisions.[24] It is the second set of standards to which trainers will need to turn their attention in the training as these are not easy to understand, have been oversimplified in the first year of the statute's implementation, and present significant implementation challenges. In addition, the trainers need to instruct ethics committee members that these standards do not mirror the standards for issuance of DNR Orders under Article 29-B of the Public Health Law,[25] now repealed. The medical futility language in the old law has been eliminated from the new decision-making standards, in addition to other changes in the standards.[26]

In this brief article, it will be impossible and impracticable to dissect these standards in any depth. However, let me highlight what will need to be reviewed in depth with ethics committee members. First, the members of the committee must have some working familiarity with clinical terminology such as what is meant medically by an illness or injury which can cause death in 6 months, an irreversible or incurable condition, permanent unconsciousness, and withdrawal or withholding of life-sustaining treatment, a defined term in the statute. In addition, committee members must be instructed that there is no legal or ethical distinction between withdrawal or withholding of life-sustaining treatment, a central constituent of the existing legal and ethical consensus in health care decision making.[27]

It is helpful in the training session to adopt a heuristic method by describing the life-sustaining treatment decision standards as broken out into two "buckets." In each bucket, the standard has two parts that have to be parsed: an assessment of burden that will be made by the surrogate, and a clinical determination that will be made by the physician. Although the statute does not clearly define this line of demarcation, there is a working consensus among health care attorneys that this is how the standards should be implemented based upon legislative intent. There is no language in the statute that bars the surrogate and the physician from consultation and such consultation likely occurs in practice, and should be encouraged to foster good communication and avoid disputes. There is also no bar in the statute to consultation with other members of the interdisciplinary team. Such consultation is also good practice.

Turning to the clinical determination first, it is helpful to present examples of clinical situations to ethics committee members and discuss whether the clinical criteria in either or both buckets would be met for the purpose of a surrogate decision to withdraw or withhold life-sustaining

treatment. For example, a patient or resident who presents with diagnoses of congestive heart failure, coronary artery disease and advanced peripheral vascular disease is likely to meet the clinical criteria of an irreversible or incurable condition as determined by the attending physician with a physician concurrence, even though the patient may not be permanently unconscious or may not be expected to die within 6 months. Ethics review committee members serving in nursing homes will need to understand that decisions (other than CPR) made by surrogates in nursing homes that fall into the "neither terminally ill nor permanently unconscious" bucket are mandated reviews requiring a binding decision of the committee.

The second part of the analysis to walk the committee members through is how to parse the assessment of burden under the decision-making standards. This section of the statute may prove to be the biggest implementation challenge for surrogates, health care professionals and ethics committee members for a number of reasons. Number one, there has generally been a very narrow construction of what these standards mean and a judgment among some health care professionals that they may be operationalized in the same way as the standards under the old DNR law. This is incorrect and would result in a serious denial of patient rights under the statute. These standards broaden the assessment of burden to the patient that needs to be made under the law. The medical futility language has been eliminated from the standards. The movement away from a medical futility standard for life-sustaining treatment decisions is a positive step as medical futility by definition and in clinical practice means success or failure of a treatment, and provides too limited a basis for weighing benefits and burdens to the patient. The medical futility standard under the old DNR law was never intended to be the basis of an assessment about quality of life.

More specifically, a whole reading of the FHCDA standards makes clear that the assessment of burden is a qualitative assessment and one that takes into account the subjective experiences of the patient. Although in the first bucket, the language of extraordinary burden does parallel the language of extraordinary burden in the old DNR law, the nature of the assessment is not tied to the patient's medical condition alone as it is in the old law but involves a multidimensional assessment of the patient.

Similarly, the assessment of burden to the patient under the second bucket is a qualitative one and multidimensional, extending to pain, suffering or burden that would be experienced by the patient as inhumane or extraordinarily burdensome. Given the knowledge we are gaining every day about pain and the experience and meaning of pain to patients in serious illness, the inclusion in the statutory language of assessment of pain burden to the patient should be welcomed.

We know based upon research evidence that pain is often untreated and undertreated, and that uncontrolled, intolerable and intractable pain leads to suffering.[28] Education provided to ethics committee members about what is involved in a multidimensional assessment of illness burden, pain and suffering under the provisions of the FHCDA will be critical to their proper and full review of matters that require provision of advice, recommendations and binding decisions.

A More Humanistic Response to Conflict Negotiation and Resolution

One of the central roles of the ethics review committee is addressing conflict and assisting in the resolution of conflict. Conflict may arise within families or between health care professionals, or from communication breakdowns between the patient, family, surrogate and health care professionals. Facilities should have procedures in place to address and negotiate conflict informally through appropriate process. However, when conflict does reach the ethics review committee, the members of the committee need to have a foundation in understanding the relational dimensions of conflict, and the significant role communication plays in helping to resolve disputes. Research evidence suggests that communication is founded upon relation-centeredness.[29] Therefore, education in the relational framework of decision making is likely to foster improved communication skills in dealing with conflict and a more humanistic, empathic response to conflict.

This is a core area of the educational curricula that draws upon interdisciplinary knowledge and expertise in work with families. Sources of conflict in families may stem from distrust of the health care system, not receiving sufficient or well explained information about the patient's diagnosis, prognosis, disease trajectory, or goals of care, and values differences. Palliative care and hospice have a well established record of supporting distressed and grieving families in the decision-making process. And the interdisciplinary team in hospice is a model of collaborative practice that can be replicated in other clinical settings.

Conclusion: Best Practice and Recommendations for Research

In bringing to close the training provided to ethics committee members regardless of what it has been possible to cover due to time constraints or other barriers, it would be important to help the group reach consensus about what is best practice in the particular facility for assuring ethically competent functioning of the ethics committee, and consultation and communication with family members, surrogates and health care professionals.

I recommend that training professionals work with facilities to develop a research agenda that will support ethics committee functions through ongoing data collection and analysis that target measurement of outcomes. The implementation of the FHCDA provides a unique opportunity for health care professionals to collaborate with health care providers in developing an evidence base that evaluates ethics training for ethics committee members and heath care professionals working in health care settings and the impact of such training on process and outcomes for patients.

Professionals who are knowledgeable about the FHCDA and the principles discussed above, including knowledgeable health care attorneys, can make a significant contribution in providing comprehensive education to ethics review committees as part of the implementation of the FHCDA and the PCIA, and in restoring the centrality of ethics and collaborative practice to health care decision making.

Endnotes

1. *See* Sarah Murray, *The quality of death: Ranking end-of-life care across the world* (Economist Intelligence Unit Lien Foundation, 2010).
2. N.Y. PUBLIC HEALTH LAW, ART. 29-D §2997-c (PHL).
3. PHL §2994-m.3.
4. PHL §2994-m.1.
5. PHL §2994-m.3.
6. *See* Timothy W. Kirk & Margaret M. Mahon, *National Hospice and Palliative Care Organization (NHPCO) Position Statement and Commentary on the Use of Palliative Sedation in Imminently Dying Terminally Ill Patients*, Journal of Pain & Symptom Management, 2010.
7. PHL §2997-c.2.
8. PHL §2997-c.2.
9. *See* J.J. Fins, *A palliative ethic of care: Clinical wisdom at life's end* (Jones and Bartlett Publishers, 2006). Joseph J. Fins, MD, is Chief of the Division of Medical Ethics of the Weill Medical College of Cornell University and Director of Medical Ethics of New York Presbyterian Hospital-Weill Cornell Medical Center, New York, New York.
10. *Id.*
11. *See* Mary Beth Morrissey, *Phenomenology of pain and suffering at the end of life: A humanistic perspective in gerontological social work*, Journal of Social Work in End of Life and Palliative Care, January 2011.
12. *See* NATIONAL CONSENSUS PROJECT FOR QUALITY PALLIATIVE CARE (2009), What Is Palliative Care? http://www.nationalconsensusproject.org/WhatIsPC.asp; Center to Advance Palliative Care, www.capc.org. Diane Meier, MD, FACP, is Director of the Center to Advance Palliative Care, a national organization devoted to increasing the number and quality of palliative care programs in the United States.
13. *Cruzan v. Director, Missouri Department of Health*, 497 US 261 (1990).
14. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §§ 4206, 2751, 104 Stat. 1388 (1990).
15. PHL Article 29-C.
16. *See* J.J. Fins, *A palliative ethic of care: Clinical wisdom at life's end* (Jones and Barlett Publishers, 2006); Mary Beth Morrissey and Bruce Jennings, *A Social Ecology of Health Model In End-of-Life Decision-Making: Is the Law Therapeutic?*, 11 (1) N. Y. ST. B. A. HEALTH L. J. SPEC. ED.: SELECTED TOPICS IN LONG-TERM CARE LAW 51 (2006).
17. *See* Mary Beth Morrissey and Bruce Jennings, *A Social Ecology of Health Model In End-of-Life Decision-Making: Is the Law Therapeutic?*, 11 (1) N. Y. ST. B. A. HEALTH L. J. SPEC. ED.: SELECTED TOPICS IN LONG-TERM CARE LAW 51 (2006).
18. PHL § 2994-m.2(c).
19. PHL § 2994-m.2(b).
20. PHL § 2994-m.2(a).
21. PHL § 2994-m.2(c).
22. PHL § 2994-m.2(c).
23. PHL § 2994-d.4.
24. PHL § 2994- d.5.
25. PHL Art. 29-B.
26. However, proposed amendments to the FHCDA would restore the medical futility standards for DNR orders.
27. Alan Meisel, *The Legal Consensus About Forgoing Life-Sustaining Treatment: Its Status and Its Prospects*, 2 (4) KENNEDY INST. ETHICS J. 309 (1993).
28. See Mayday Fund Report, *A call to revolutionize chronic pain in America: An opportunity in health care reform*, (Washington, D.C., 2009). This report was funded by the Mayday Fund, a family foundation committed to reducing human suffering caused by pain. Russell Portenoy, MD, one of the principal authors of the report, is Chair of the Department of Pain Management and Palliative Care of Beth Israel Hospital and Chief Medical Officer of Metropolitan Jewish Hospice and Israel Hospital and Chief Medical Officer of Metropolitan Jewish Hospice and Palliative Care and Jacob Perlow Hospice. *See* StopPain.org, Department of Pain Management and Palliative Care web site.
29. *See* David, Y. F. Ho, *Pooled Peer Ratings, Self-Ratings, and Estimated Ratings of Therapeutic Communication and Popularity: A Relational Analysis*, Humanistic Psychologist, 38(4), 317-335.

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Bioethics Consultation Before and After the Family Health Care Decisions Act

By Tia Powell, M.D. and Hannah I. Lipman, M.D., M.S.

Consultation Request[1]*: Mr. A is a 74-year-old man who has a history of hypertension. Three months ago he suffered a large stroke which left him half paralyzed and unable to swallow effectively or speak. He was discharged to a subacute rehabilitation facility with a feeding tube. He did not recover any cognitive, motor or speech function. Two weeks ago he was admitted to the hospital with pneumonia. He was treated with antibiotics and was placed on a mechanical ventilator because of respiratory distress. His infection is severe enough that he requires fluids and medicines to support his blood pressure. Now his mental status is significantly worse than his poor baseline. He occasionally opens his eyes, but can't follow commands. He grimaces when experiencing discomfort, such as when the nurses suction his breathing tube.*

Mr. A is from the Dominican Republic. He has been married for 51 years and has 4 children, all of whom were raised in the US. He has no health care proxy or living will. His children have been making medical decisions for him since the stroke. They report their mother is "nervous" and request the team not give her any information about her husband's condition, although she visits every afternoon. When the ICU team approached one of the patient's children for consent for a tracheostomy, a procedure to enable long-term ventilator support, she declined, reporting "my dad wouldn't want to live this way." The team has observed strained relationships among the children and they are also concerned about the role of Mrs. A as a decision-maker. They request Bioethics Consultation.

The historic passage of the Family Health Care Decisions Act (FHCDA) rights a great wrong in New York law. In the nearly two decades that it took to pass the FHCDA, countless family members were excluded from the process of making medical decisions on behalf of their loved ones, and witnessed care that appeared to violate the values and wishes of patients. Spouses of 50 years had no formal standing to shape the goals of care for a beloved husband or wife. A small minority could produce "clear and convincing" evidence and so participate, but the majority of families were left without sufficiently explicit instructions. Today families still rely on clear evidence when it exists, but they are also free to consider patients' lived experience, values and best interests when called upon to make decisions for those who no longer can.

And yet no law can make end of life decisions easy. Unhappy families are not alike, and find a seemingly endless number of ways to disagree, including about the appropriate care for an incapacitated loved one. The case described above (an anonymized composite of many cases) is difficult precisely because this patient has not left clear and convincing evidence of his wishes. Of note, patients from minority groups are less likely than others to complete advance directives.[2] This difference along racial and ethnic lines in expressing end of life choices was part of the injustice of New York's former reliance on clear and convincing evidence. The most vulnerable were further disadvantaged by a system that favored documentation. FHCDA paves the way for broader family engagement in surrogate decision making for incapacitated patients. How do these changes play out in the clinical world, and how have they shifted the practice of bioethics consultation?

Our answer to these questions stems from our specific work setting. Knowing that the impact of the FHCDA may be different at different facilities, we describe the practices of the Bioethics Consultation Service at Montefiore Medical Center, where both authors work. This service was one of the first founded in the U.S., begun in 1978 by attorney Nancy Dubler. Today the service flourishes as among the most active in the country, with roughly 300 yearly consults arising from the 1,500 beds of our multi-part hospital. We are not called for routine DNR decisions, hospice transfers, or discussions to set goals of care; our colleagues handle these important conversations as part of their regular duties in caring for patients. We are called when there are values conflicts among families, patients, and health care providers about a significant health care decision, or when those involved are simply not sure what is the right thing to do.

For most of our cases, we rely on a single well-trained and experienced bioethics consultant, rather than a small team or full committee. The consultant confers with all those involved in the case, including family and staff, and pulls together the resources needed to resolve the dilemma. Our consult process emphasizes the resolution of conflict among appropriate stakeholders, including providers,

patients and families. We rely on a single consultant to mediate conflicts because adding extra members to the process on the side of the professionals may diminish the voices of those with a genuine role, and in particular may drown out the voices of patients and families in favor of those who work together as professionals. We also find that for a service with our large volume this single consultant model works best; the labor demand to provide multiple staff members for hundreds of yearly cases would be overwhelming. The use of a single consultant places great pressure on our consultants to make sure they do not impose their own values, but rather competently mediate among the providers, family members and others interested in the case. We suspect that the single consultant model is not appropriate for every institution. It requires substantial training and experience for all consultants and is best suited to a facility that can commit sufficient resources.

We will provide here only a brief overview of our consult practices. In providing a bioethics consultation, we focus first on trying to understand the values and preferences of the patient. Whenever possible we visit patients and interview them if they are able to participate in a conversation; this direct experience informs us in ways that others' descriptions cannot. We provide an opportunity for all those involved to articulate their values. Frequently, though not always, this opportunity takes the form of a meeting that includes staff members, family, and the patient when capable of participating, during which the bioethics consultant mediates and facilitates. We help determine the range of ethically and legally acceptable choices and work to facilitate a consensus within that framework. When indicated we consult with attorneys or do research to clarify medical, ethical and legally acceptable options. We document our work in the hospital record. Rather than making pronouncements, our notes aim to reflect the work of building consensus around the best course of action for this particular person and to educate team members about common ethical dilemmas. Cases are presented every other week at Consultation Rounds. A summary of monthly consults and an in-depth discussion of one or more challenging cases occur during the monthly meeting of our full Bioethics Committee.

In this context, then, let's examine the ways in which FHCDA has and has not changed practices within our bioethics consultation service. FHCDA calls for the formation of an Ethics Review Committee (ERC) composed of a minimum of five persons, including a doctor, a nurse and one member not employed by the institution. Clearly our practice of relying on a single consultant does not adhere to this model, so how are we to align our practices with FHCDA? We take two complementary approaches. We note that the Act permits a facility to use "less formal" means of resolving ethics conflicts, and we view our well-established consultation service as falling within that category. We anticipate that the great majority of situations will be resolved by this means, as has been the case at our institution for decades.

However, an ERC is required for specific types of bioethics dilemmas, for instance those in which an emancipated minor wishes to forgo life-sustaining treatment. For these required uses of the ERC, as well as for those cases in which our usual consultation format fails to provide an acceptable resolution, we have established a means of providing an ERC. When circumstances require, we will call upon the roughly three dozen members of our Bioethics Committee, which includes all members of our Bioethics Consultation Service, as well as several members who are not employed by the hospital. However, these external members, by definition, are not typically present at the hospital on a regular basis. Because the circumstances requiring an ERC may include highly time-sensitive cases, we devised two mechanisms for dealing with a potential short-fall of external members. First, we note that the FHCDA does not require members of the ERC to be physically present to participate. We will permit telephone participation as needed to facilitate the timely resolution of cases. Second, our institution has provided bioethics training in the New York area for nearly twenty years through our Certificate Program in Bioethics and more recently the Master of Science in Bioethics. We have an email list of members of our alumni network who would be willing to serve on an ERC at a facility other than their own. Should an ERC be needed, we will put out a request for a participant and select the first appropriate respondent. We have also used these resources to help a number of New York institutions find either permanent or ad hoc external members for their ERCs.

But what of a patient like Mr. A, described above? How has the FHCDA changed the options for an incapable patient without advance directives or other clear and convincing evidence? Before the passage of the FHCDA, any attempt to make decisions on behalf of such a patient stood on shaky legal ground. Bioethics consultants could meet with families and encourage them to search the house for proxy forms or living wills that might have gone unnoticed. Then and now bioethics consultants do sometimes unearth advance directives from previous hospital admissions that help reveal the patient's preferences. Unfortunately, the majority of patients do not have written advance directives and many of our patients are reluctant to complete them. Bioethics consultants would urge family members to try and recall past conversations

in which the now incapacitated patient expressed clear preferences about end of life choices. In these cases, pre-FHCDA, bioethics consultants faced an uncomfortable ethics dilemma of their own. What should they do when a loving family, apparently acting in the patient's best interest, strongly insisted that the patient would not want life-sustaining treatment, yet could not provide clear and convincing evidence that met the standards of New York law?

Bioethics consultants dealt with a series of unacceptable choices. They could choose to interpret statements as clear and convincing that did not conform to the standards developed in state case law. In some cases, this stretching of standards may have produced an outcome that did the right thing by the patients without clearly violating the law. In other cases, consultants and family members were tempted to actually manufacture evidence, perhaps in the form of conversations that either never occurred or whose contents were significantly altered in order to meet legal standards. For obvious reasons, no data exist on the number of times that consultants, physicians and family members colluded to circumvent a bad law, but there is little disagreement about whether this occurred.

Of course, breaking the law by manufacturing evidence was never the only choice. Additional bad choices, pre-FHCDA, remained. The patient could simply continue with life-sustaining treatment, even when family and physicians strongly believed that such treatments were contrary to the patient's preferences and/or best interests. The option of requesting a court order to withdraw life-sustaining treatment also existed, at least as a theoretical possibility. However, courts are not generally able to respond at a pace that is consistent with a patient's need for medical decisions. If hospitals requested a court order for every decision regarding life-sustaining treatment for an incapacitated patient, the volume of cases would choke the system to a halt. Before the passage of the FHCDA, for patients like Mr. A, there were essentially no other options clearly supported by New York law.

How has FHCDA changed the process of making decisions on behalf of a severely ill patient like Mr. A who has not left evidence of his preferences? The law has made possible—though not easy—a resolution that corresponds to Mr. A's values and meets appropriate goals of care, as articulated by both the family and the health care providers. Let us walk through the steps that a consultant at our facility would take in resolving the dilemma of how to care for Mr. A. First, the consultant would review the chart to obtain as accurate as possible a view of Mr. A's clinical situation and potential choices, including any history of his expressed preferences. We review the chart because we do not find satisfactory a quick verbal summary of the case, which may leave the consultant without enough information to question statements like, "there's really nothing left to do for the patient," or "this family is unreasonable."

Having gathered data from the medical record, our consultant would most likely move on to speaking with the various participants to test and improve this growing body of information regarding Mr. A. Of note, we do not limit those conversations to staff and professionals, but explicitly seek out family members, who remain the experts on Mr. A's values and preferences. If there is a family member who has a reasonable right to involvement in the decision yet who has proved difficult for the staff, we are far more, rather than less, likely to speak with this person. As the consultation proceeds, we are particularly eager to work with those who might otherwise un-do the difficult work of building consensus. Our style of resolving bioethics dilemmas focuses on ensuring an inclusive and ethically viable process, rather than on simply providing a "right answer" generated primarily by the consultant. While the consultant works to build consensus, he or she also helps define the list of ethically, legally and clinically viable solutions.

As the consultant proceeds, she builds a mental list of issues and concerns raised by staff and family. For instance, the patient's children want to protect their mother from the burden of making end of life decisions for their father. However, Mrs. A clearly comes first in the FHCDA hierarchy of decision-makers; a solution will need to address the tension between these two apparently conflicting goals. The consultant finds that the patient's four children do indeed have different ideas both about who should decide for their father and what those decisions should be. The consultant will need to establish a mode of making surrogate decisions that is legally viable and acceptable to the family. Options include: the mother as sole decision-maker, the mother and children as joint decision-makers, the mother defers and the children decide as a group, the mother defers and the children coalesce around one sibling as the lead decision-maker. The consultant will likely need a family meeting to help discover which of the options above is most appropriate for Mr. A's family. Ironically, FHCDA restores the legal basis for providers and families to craft a sensitive and sensible method of surrogate decision making that fits the needs of the individual patient, much as they might have done in generations past.

The consultant's mental list also includes questions about *what* issues should be decided, in addition to who should decide. The original request focused on the issue of tracheostomy, but this is unlikely to be the single diffi-

cult decision regarding this patient. Further conversation reveals that the attending physician believes the patient should have a DNR order and move out of the intensive care unit, but is wary of raising this issue when the decision-maker is unclear and the issue of consent for a tracheostomy appears stalled.

The consultant decides to hold a meeting with the family and the team together. However, she first must determine how to address the family's concerns about protecting Mrs. A from the burden of deciding for her husband. The consultant finds Mrs. A and one of her daughters at the bedside. She speaks with Mrs. A for some time about her marriage and children. The consultant then observes to Mrs. A that it is very challenging to make decisions on behalf of a loved one. She notes that some people want to take on this task, while others would rather give this job to another loving family member in order to focus on other tasks, such as supporting the patient or praying for his recovery or for guidance. Good people may choose differently and either choice is legal and ethical. The consultant asks Mrs. A if she would prefer to make decisions for her husband or have her children make these decisions. Mrs. A responds that she would like to make the decisions, but that she would like help from her children. Mrs. A also notes, looking clearly at her daughter, that she knows Mr. A's "time is coming" and that she will be a good wife by helping take care of him when he needs her most. Partly for the benefit of Mrs. A's daughter, the consultant summarizes and emphasizes Mrs. A's comments, noting her desire to participate in decision making and her knowledge of Mr. A's mortality. She adds that Mrs. A is in fact the next of kin and has the right to make these decisions if she chooses. The consultant asks the daughter to let her siblings know about this conversation and invite them to the bioethics meeting.

At the bioethics meeting, the consultant helps all participants review Mr. A's values and preferences and his clinical situation. Typically she will ask the family to speak about Mr. A, to give the clinical team a more nuanced understanding of who he is, including his values and preferences. More often than not, clinicians for patients like Mr. A have no knowledge of him before his current hospitalization and incapacity. The most involved physician will then provide a summary of Mr. A's condition so that all are up to date. As needed, the consultant will serve as translator of medical jargon to assure that the family understands key details and the overall context of the patient's clinical circumstances. The consultant also summarizes the earlier conversation, noting Mrs. A's desire and right to act as the surrogate, but also to receive support from her children in the difficult task of making surrogate decisions. Taking these values and medical facts into consideration, she will help the group agree on goals of care. The family comes to accept that Mr. A is likely to die, perhaps within the next few weeks, given the burden of his illnesses. They would like him to be comfortable, but not to have his life shortened. The family is initially quite divided about the need for tracheostomy, since all agree he would not want to live for a long period on the ventilator. Mrs. A, however, cannot agree to the option of immediate extubation, as she finds this too close to causing his death. The family agrees to tracheostomoy as a palliative measure, to keep him more comfortable in what are expected to be his remaining weeks. Some of Mr. A's children might have opted for immediate extubation, and they take great hope in the fact that they can re-visit this possibility in some weeks if it appears Mr. A is suffering without an end in sight. Having settled this issue, the one for which the consultation was requested, the consultant raises the issue of a Do Not Resuscitate order (DNR). With substantial discussion and clarification of the meaning of DNR, Mrs. A, supported by her children, agrees that a DNR order is appropriate for Mr. A. Mrs. A is not ready now to opt for hospice care but would like to learn more about it and will consider this option if Mr. A lingers longer than a few weeks. The family agrees to learn more by referral to the palliative care consultation service.

Returning to the question of how consultation differs now from before the passage of the FHCDA, let's review the family's choices on behalf of Mr. A. They could have settled upon the DNR order, just as they did in this case. They could have agreed to tracheostomy. They would not have had the option of considering withdrawal of life-sustaining treatment, but would have been told that Mr. A must remain on the ventilator until his death, despite their views of his suffering or preferences. This change, not in what the family actually chose but in the sense of hope and comfort provided by a true choice, makes all the difference. For surrogate decision-makers who do choose to forgo such treatments as ventilation, dialysis or other high-tech interventions, they no longer suffer legal barriers to doing what they believe is right for their loved ones.

On balance, FHCDA improves the decision-making process for patients like Mr. A. There are other circumstances in which FHCDA may not change decisions for the better. Patients who lack decision-making authority yet object to the designation of a surrogate or to treatment decisions made on their behalf by such a surrogate may demand a court order before treatment can proceed. Our consult service has worked with patients who suffer from paranoia, lack decision-making capacity, have urgent need for medical treatment and yet object to the appoint-

ment of a surrogate. The often urgent time frame of clinical decisions means that court orders are an imperfect means to resolve disputes. We suspect there could be problems in the near future due to this aspect of FHCDA.

Bioethics consultation before and after the passage of the FHCDA remains challenging because of the complex clinical and emotional choices at hand. Decisions about end of life care were never easy, and are unlikely to become so through the passage of any law. Family members and providers do and should weigh with the utmost care those choices that are clinically realistic and ethically and legally acceptable options for patients in their final days and months. FHCDA has removed some unnecessary barriers to decision making by permitting families to incorporate patients' values and lived preferences into these crucial choices.

Endnotes

1. To protect patient confidentiality, the case of Mr. A is a composite based on the experience of the Montefiore Bioethics Consultation Service.
2. U Braun, R Beyth, M Ford, L McCullough, "Voices of African American, Caucasian, and Hispanic Surrogates on the Burdens of End-of-Life Decision Making," *J Gen Intern Med* 23(3):267-74.

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Ethics and Clinical Practice Guided by the Family Health Care Decisions Act

By Mathew Varughese, Ross Wilson, M.D., James Zisfein, M.D., Allen Keller, M.D. and Nancy Neveloff Dubler for the New York City Health and Hospitals Corporation Bioethics Council

I. Introduction

A. A Word on Process Within the New York City Health and Hospitals Corporation (HHC) Bioethics Council

Bioethics is a field forged from disparate disciplines and the voices of various stakeholders. It combines the moral commitments of medicine and the logic of judicial opinions, legislative enactments and legal scholarship with religious commitments and social critique. Thus, bioethics is, by nature and by necessity, a collaborative enterprise requiring various joint exercises designed to surface agreement and disagreement and work toward consensus.

What follows is a set of ethical principles and commitments that were developed by the HHC Bioethics Council in response to the Family Health Care Decisions ACT (FHCDA), for the guidance of decision making at HHC facilities. The Council is composed of all of the chairpersons of all of the institutional ethics committees at each of the hospitals and long-term care facilities of the HHC system. Needless to say these constituent components of the HHC organization address some similar and some very different sorts of moral quandaries given their locations in the city and the populations that they serve. These guidelines are clearly not law; indeed they are structured to be a companion and counterpoint to the law. They focus attention on how to think about the issues and about the interests, rights, feelings and emotions of those parties involved in the process of making decisions for incapacitated and immature patients. They are not intended to be fixed and rigid but rather to be flexible and supportive of patients, family members and medical care providers who must now, together, face the weighty matter of deciding for others.

Not all of the listed authors nor all of the chairpersons of all of the ethics committees agreed on every word presented in this discussion. They all did agree that they could stand by and support this document as an aid to teaching and training providers in the ethics of implementing the new FHCDA.

B. A Word on New York State Legal History and Process

Over the last two decades New York state law has existed in escalating tension with evolving practices in medicine addressing care for decisionally compromised patients at the end-of-life. A 1981 New York judicial opinion had determined that the only legally sanctioned standard for withholding or withdrawing care from a patient at the end-of-life required that: (1) the patient had been previously capable of making health care decisions; (2) the patient had left an explicit directive determining future care; by (3) clear and convincing evidence.[1] This decision, importing legal language and concepts into the practice of medicine, reflected the legal struggles of the time to fashion rules governing decisions about death and dying. State courts from New Jersey to Massachusetts to California were then struggling to fashion rules that would be just and fair, would support the powerless, and would measure and value the increasing ability of medicine to sustain life against those interventions that merely prolong the process of dying.

During this engaging national discussion New York State was hindered in its medical-legal dialogue by a standard for decision making that failed to reflect how patients actually plan for their futures and how medicine is practiced. Numbers of studies documented the unwillingness, inability or ethnic disinclination of patients to indicate their wishes for care in the future were they to be incapacitated. Medicine evolved a robust and supportive sub-specialty of Palliative Care to focus on comfort and dignity of the patient that encouraged physicians, patients, and family members to assess whether aggressive interventions were less individually desirable and less medically appropriate as the burden of the intervention increased and the benefit diminished. Ultimately, as death moved inevitably closer, comfort care and palliation, rather than aggressive interventions, came to characterize "best practice." The FHCDA is a corrective legal framework that supports this evolved good medical practice.

II. Ethics Principles Guided by the FHCDA

The ethical principles and precepts that follow can be used to guide physicians and other health care professionals as they care for patients at the end of life. These ethical discussions are based upon the legal standards set forth in the FHCDA. It is our hope that these principles will help physicians and other health care providers to link the law with good clinical practice.

1. The Family Health Care Decisions Act [FHCDA] Is a Platform for Clinicians and Medical Care Teams to Provide Better Care for Patients by Respecting Their Values and Supporting Their Family Members and Loved Ones

1.1 The FHCDA empowers family members and others close to the patients, who know the patient's values, to make medical decisions when incapacity intervenes.

The FHCDA recognizes the stark and well-documented reality that patients, by design or by inadvertence, often fail to designate a health care proxy or to leave explicit directions about their wishes for medical care if they become incapacitated. Responding to this fact, the act enables family members and others close to the patients to make medical decisions in accordance with the patient's wishes. If the patient's explicit wishes are not known, the FHCDA directs the surrogate to make decisions in accordance with the patient's values and past patterns of behavior including the patient's religious and moral beliefs.[2] The surrogate has all the powers an individual patient would have to make his or her own medical decisions, including the decision (under most circumstances) to withhold or withdraw life-sustaining treatment.[3]

1.2 The FHCDA empowers surrogates [family members, loved ones and domestic partners] but, by implication, imposes enhanced obligations on physicians to communicate sympathetically and effectively, to evaluate medical data and state the prognosis honestly, and to be truly open to the discussion of patient values even when these may conflict with medical culture.

Physicians must:

- Utilize "shared decision making" with the surrogate;
- Discuss medical condition and prognosis clearly, honestly and humanely;
- Recognize that family members and loved ones may be overwhelmed by feelings of responsibility and uncertainty;
- Understand that surrogate fears and family dynamics may act as barriers to clear consideration of options;
- Be aware that central to supporting surrogate decision makers is reminding them that they are making decisions to the best of their ability in accordance with the patient's wishes. This perspective requires framing questions to the surrogate in terms of what the surrogate believes the patient would want or not want done, rather than merely asking the surrogate what to do.

1.3 Surrogates, legally appointed under the FHCDA, have thrust upon them the awesome responsibility of deciding for others and require communication, compassion and support from the care team to carry out their responsibilities.

The fact that many surrogates will be appointed by the law rather than selected by their loved one demands that they be informed, supported and protected as they confront this arduous duty of deciding for others. The law also requires such communication.[4] For many surrogates, the process will pose extraordinary and unfamiliar burdens. Medical care providers daily confront decisions that may result in pain, suffering, and even death for a patient. They do so because, in their judgment, the route chosen offers the best hope for the patient's return to a prior state of robust health and functioning. The burden of care and the pain and suffering that may accompany the interventions are morally justified by the expectation of benefit. This is the calculus that providers and patients make together during the process of informed consent nested in a structure of shared decision making.

Legally appointed surrogates must be brought, as the patient would be, through this thicket of issues and considerations that comprise medical decision making. They must be helped to identify the values of the patient as the basis for the choice, and when that search fails, be helped to understand what is in the best interest of the patient. The notion that what is best for the patient may be to provide comfort care and not to contest the process of dying will pose a cognitive and emotional chasm for some surrogates. Discussion of the prognosis in light of the patient's patterns of life and personal values and a focus on palliative care may help to vault this divide between the understandings of the team and the position of the surrogate.

1.4 In health care, making decisions for others may be more stressful for the agent or surrogate than making decisions for oneself.

When the patient herself is making a decision she can:

- Balance the identified risks and suggested benefits of care in the context of the diagnosis and prognosis,
- Measure these against her own history, values and religious preferences,
- Assess a willingness to take risks against the possibilities and probabilities of a particular outcome,
- Evaluate the ability to withstand pain and suffering for a future possible benefit,
- Review the costs of the intervention and consider the possible effects of this expenditure on others,
- Consider all of these issues in the context of the moment and for the future,
- Confront whether the intervention, in a life-threatening situation, is preferable or whether, given all of the circumstances, acceptance of comfort care and the inevitability of death seems more in concert with a life lived. While ambivalence about death is understandable, some choices seem worse than a medically supported end to suffering.

Doctors and patients have struggled with these difficult decisions for decades. The core of the doctor-patient relationship is the ability of the physician to focus the attention of the patient on these personal, morally and intellectually complex issues. The process of "informed consent" is the process in which the patient learns about the risks, benefits, and alternatives for different interventions, the risk of non-intervention, and the likelihood of death. The patient can then mix and measure these medical data in the personal cauldron of a life-lived, to reach a decision that can be communicated to the physician as she provides guidance to the care team regarding future treatments.

It may be, however, that this personal calculus for another is more stressful than considering the issues for oneself. If it is the patient who is experiencing the suffering then she can weigh the alternatives with some personal surety that the balance reflects her position. But if it is a surrogate weighing pain and suffering second hand, in the abstract for the patient, consider how significant is the matter of a mistake. This awesome responsibility may be thrust, unanticipated and unwelcome, on a relative or loved one of the patient, for which sympathy, support and compassion must be the response of care providers.[5]

1.5 The doctor-health care agent and doctor-surrogate relationship has not received the attention accorded the doctor-patient relationship but it is central to the fair and just implementation of the FHCDA.

The health care proxy is a known feature of NYS law. Agents under a proxy have been appointed by patients for decades to explain and extend their wishes and desires and to protect their rights and interests when incapacity intervenes. Even though NYS law does not require a patient to inform a person who is appointed as a proxy, most patients do so as a way of advancing their personal preferences. But deciding for others is a profound and taxing burden, even for a person who has been prepared for the task by discussions over time with the patient. The proxy can never be certain that what she advocates for would reflect the wishes of the patient. When the burdens are overwhelming and the benefits slim, the decision to choose hospice and permit death is one that can never be easily or comfortably confronted for another.

In the world of surrogate choice it is the obligation of the physician and the health care team to support the surrogate, to provide information, and to offer solace and consolation when the choices are limited.

1.6 Shared decision making is central to the implementation of the FHCDA. The art of the doctor-surrogate relationship is for the physician to share with the surrogate all information that she would share with the patient if the patient were capable of making health care decisions, and in addition, to bear the burden of hard decisions without disempowering the surrogate.

The true art of medicine is to present the data, discuss how the data intersect with the life, or possible death, of the patient and bear the burden of the choice that accepts death while yet permitting the surrogate to feel empowered. Medical staff deals with the death of patients daily; family members and loved ones do not. Personal values determine choice but only from the menu of options realistically available to this patient. Surrogates must not be made to feel that the patient's death was their "fault;" death is the inevitable end of existence. Care, comfort and dignity are the focus at the end-of-life and the surrogate must be permitted to share in benefit of these assistances and not in the burden of the death itself.

2. Decisional Incapacity and Standards for Decision Making

2.1 Central to the notion of decisional incapacity is the fact that capacity can be clearly present and uncontroversial or uncertain and deeply problematic.

Capacity may be declining, fluctuating or wavering and may include "windows of lucidity" that emerge from what appear to be disconnected thoughts and utterances. Decisional capacity is also "decision-specific" as a patient might be capable of making a decision of little risk or complexity and not capable of making a complex decision that allows for the possibility of disability or death.

Adults can exhibit fluctuating or intermittent capacity, dependent capacity, supported capacity and—most puzzling, at times—windows of lucidity in otherwise cognitively opaque states. This makes the process of determining capacity or incapacity one of the keystones to its utility as a legal and ethical concept. An examination at one moment of time, by one care provider, may not be adequate to determine the status of the patient along the spectrum of decision-making abilities. As required by law, observations by the care team over time can be of greatest support to the physician whose role is to determine and document capacity or incapacity.[6]

Under the FHCDA, decision-making capacity means the ability to understand and appreciate the nature and consequences of proposed health care, including the benefits and risks of and alternatives to proposed health care, and to reach an informed decision.[7] Ethically, the patient must be able to relate to the diagnosis and prognosis of her illness; to apply personal preferences to choose among options for care; and to communicate her decision to her medical providers in order to guide future interventions.

- ***Context matters***. In many cases patients are clearly capable or incapable of making choices about care. A patient, who is moribund, obtunded, intubated and sedated, who has been so over time and will continue in this state, is clearly not capable of participating in decisions. On the other hand a patient who is merely intubated and sedated might have the sedation lifted to attempt participation. Decision-making capacity may fluctuate over time because of a variety of factors.
- ***Care providers matter***. For example, skilled clinical assessment can assist in determining delirium or identifying mental illness that may be interfering with cognition and comprehension. This will be especially important if the condition may be amenable to treatment that could improve the ability of the patient to participate in the future in decisions about medical care.
- ***Discussion and deliberation matter***. Medication, anxiety, depression masquerading as dementia, fear, and loneliness can singly or in combination appear as incapacity. Gathering all providers and assessing the amalgam of impressions over time will generate better decisions in difficult situations.

2.2 The FHCDA identifies the values and desires of the patient as the focal point for health care decision making. This is appropriate, as individual choices about medical care are comprised of value determinants that reflect personal history, religious preferences, and cultural commitments. This law demands that these values and desires, when communicated to providers, be respected.

Physicians and other providers must be skilled at ferreting out patient values and helping patients, and, under the FHCDA, surrogates to apply those values to the medical situation confronted.[8] Under this new law, this dynamic of the decision-making process must direct decisions made by legal surrogates. Connection to the patient matters under this law, as it should, and those appointed are morally best situated to decide for the patient. But the law will impose the burden of decision making on persons who may be untutored and unprepared for the task, thus enhancing the obligations of care, comfort and support owed by the medical team.

2.3 When specific desires, personal values and illuminating history are all unavailable, decisions should be made in the "best interest" of the patient, noting that a natural and comfortable death may sometimes be the most appropriate available option.

Often, treatment decisions must be made for patients who lack capacity and cannot decide for themselves. These may be persons who were formerly, but are no longer, capable of making decisions or individuals who never had the opportunity to form values or preferences like newborns. The standards for health care decisions for patients who lack capacity give preference to the patient's voice as the central and most widely accepted source of moral and legal authority. In some cases, the decision maker may rely on the prior stated wishes of the patient or, if these are not known or were never articulated, the wishes of the patient inferred from patterns of choice. But when neither is available, the surrogate decision maker must rely on a best interest standard.[9] This standard requires an objective assessment of the relative benefits and burdens of available treatment options.

Since this standard is employed when there is no knowledge of a particular patient's prior wishes or inferred wishes, it is primarily an impersonal standard. In the absence of such particularized knowledge, the best interest standard considers what would be most likely to benefit or promote the well being of a hypothetical patient in the same circumstances as those of this patient. Any additional information specific to the particular patient being treated might also contribute to an assessment of what is in his or her best interest. Health care teams must apply due diligence in identifying additional informants and information.

In assessing best interest, both the outcome and the probability of achieving this outcome for different treatment options should be considered.[10] In the clinical setting, the best interest standard would consider mitigating pain and suffering, prolonging life, restoring and enhancing comfort, and maximizing the potential for independent functioning. In all cases where this standard is invoked, best interest should be determined as far as possible from the perspective of the patient, not that of the decision maker.

2.4 Individual patients, when choosing among options for care, apply their own preferences, shaped by factors including their individual life's history, experience previously with medical care, religious beliefs, and moral values. Surrogates should strive to incorporate these factors.

Surrogates may have available to them the stated wishes of the patient before incapacity intervened. In many cases they have spent time with the patient and have insights into patterns of preference and habits of person. They may have some notion of whether, even without having discussed the specifics of medical care, the patient would be more inclined to accept a greater burden for less benefit or would choose comfort. People are not distinct beings for purposes of making medical care decisions. The other issues in their lives and the sorts of decisions they have displayed in widely different settings may provide some window into relevant values.

But if it is not the case that there are lessons to be learned from this person's history, or if questions remain about a preferred treatment, the FHCDA provides a wise litany of considerations for determining a patient's best interest, including:

> consideration of the dignity and uniqueness of every person; the possibility and extent of preserving the patient's life; the preservation, improvement or restoration of the patient's health or functioning; the relief of the patient's suffering; and any medical condition and such other concerns and values as a reasonable person in the patient's circumstances would wish to consider.

It is especially important in considering the notion of "best interest" that the medical team be both honest and clear, as it is supportive and comforting. It is an awesome responsibility for the surrogate either to approve of interventions that are risky and painful or permit those that will clear the barriers to death. In either event the team needs to use its skill and support to justify the medical interventions and help the surrogate to negotiate the emotional trauma of the decision.

2.5 Life-sustaining treatment presents an extraordinary circumstance in the FHCDA, as it should.

Failing to attempt to delay death should be undertaken only after a careful and conscious process that focuses the care team and the surrogate, together, on this ultimate choice. Contemporary medical practice, having survived the arrogance of success that preceded AIDS and the graying of America, has generally accepted that death is not necessarily the worst option among the choices available. Medical care often imposes pain and suffering in exchange for a promised benefit, amelioration of prior pain or chance of enhanced quality of life. But these benefits may not be available to balance the burdens of treatment. At such times, an ethical analysis must question the merits of and the basis for any intervention.

2.6 The FHCDA recognizes that under certain circumstances it may be in the best interest of the patient for surrogates to accept, and not contest, the process of dying. Factors to be considered include whether the patient would benefit from treatment and whether he/she is suffering. The care plan should always ensure compassion and caring, and may need to incorporate aggressive comfort measures even when awaiting death.

This standard articulates a shared perspective that is widely presented in bioethics scholarship, reflected in case law in other jurisdictions, and advocated by palliative care experts. It permits the logic and skills of bioethics and palliative care to be integrated into the care of patients with life threatening illnesses so that the most humane and supportive care is provided as a matter of course. The practice of medicine should not be governed by the "technological imperative" [because it exists it must be employed]. In order for an intervention to be in the best interest of the patient, it must advance the health and well being, and not simply extend individual organ function in light of a failing organism.

3. Health Care Decisions for Adult Patients Without Surrogates

3.1 The patient alone, the" unbefriended patient,"[11] is among the most vulnerable persons in the health care setting. Thus clinicians bear added responsibilities and obligations for patients without surrogates. The absence of a surrogate nonetheless requires that all care plans be considered including aggressive interventions and palliative, supportive, and comfort care. As the invasiveness or burden of the treatment rises and the prospect of benefit diminishes, the health care team should engage in thoughtful and sensitive discussion in order to parse the benefits and burdens of alternative treatments, and ultimately arrive at an ethically appropriate and comfortable result.

Patients may have some distant relative, friend, or care provider who can be contacted and some prior recorded wishes or relevant information that can be recovered. A reasonable effort should be made to identify such additional information, when possible. However, in some instances there is neither a surrogate nor any information about the patient's wishes or preferences available. Such patients are a hidden and closed box of values, history and desires. For these patients the FHCDA permits "routine medical treatment" to be decided by the patient's physician.[12] Ethically that would mean treatment that is neither experimental nor controversial and that is, in the judgment of the physician, in the clear best interest of the patient. The team, with appropriate intervention in difficult cases of a Clinical Ethics Consultant, will be able to address these decisions comfortably.

The FHCDA also addresses "major medical treatment" and even withdrawing and withholding life-sustaining medical treatment.[13] The decision making standards are the same for major medical treatment as for "routine medical treatment." However, there is an additional procedural element. Specifically, a physician can make a recommendation in consultation with hospital staff directly responsible for the patient's care. At least one other physician designated by the hospital must independently determine that he or she concurs that the recommendation is appropriate.[14]

Complying with the above will satisfy the requirements of the FHCDA. But ethically more can be done. The more concerned professionally skilled and compassionate staff comes together to discuss the case and the options, the better the discussion of alternatives is likely to be. An "ad hoc" meeting of the institution's ethics committee may lead to the exploration of all alternatives and the comfort that one is best for this patient. Collective consideration demonstrates respect for the patient and for the seriousness of the decision.

The FHCDA has delineated a limited situation where withholding or withdrawing life-sustaining treatment is authorized for a patient who does not have a surrogate. The law states that the attending physician, with independent concurrence of a second physician designated by the hospital, must determine to a reasonable degree of medical certainty that life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided, and the provision of life-sustaining treatment would violate accepted medical standards.[15] Once this threshold condition has been met, the decision-making standards enumerated for a surrogate are the same standards that have to be met by providers prior to implementing a health care decision for a patient who does not have a surrogate.

The attending physician on whom much of the responsibility, including its timeliness, for decision making falls should utilize available resources including the Palliative Care Team and the Clinical Ethics Consultation service in order to gather all of the expertise and explore all of the options. The goal of such discussion and deliberation should be to reach consensus on the best course of action and possible outcome for this patient. As with the surrogate, so too among the team, shared decision making assumes that authority and responsibility will sit comfortably together and support the best decision.

4. Decisions for Children

[This discussion focuses mainly on decisions for adults. But, some few comments about how these decisions are made for children seem appropriate. A separate discussion would be needed to explore the depth and breadth of pediatric practice].

4.1 Pediatricians and parents have a long and deep tradition of deciding together about care for children. Ethically, decisions for children must address developing capacity in the same way that decisions for adults accommodate declining, fluctuating and wavering capacity.

In general, parents and pediatricians, with increasing participation of the child as that child advances, make decisions about care for that child. Occasionally, when parents and pediatricians disagree, or when abuse is alleged, the state welfare or justice agencies become involved in weighing the evidence and determining the best interest of the child. There are also federal and state statutes that empower children under the generalized age of adulthood [generally 18] to make certain decisions about: treatment for drug and alcohol use; use of contraceptives, fam-

ily planning and abortion; and, some decisions about the care of children born to teens. Under some circumstances children of 12 or 13 have rights under these statutes.

As children age, some chronically ill children develop increasingly apparent moral and cognitive capacities to address decisions about their health care. They develop capacity to understand the context of their illness, the speculative nature of proposed treatments, and the possibilities or probabilities of success or failure of experimental interventions. They acquire information and develop an ability to evaluate present risks and immediate pain and suffering against later projected benefits.

Most young children, however, clearly need parents and guardians to make medical decisions for them. Even for small children, attempts to assign some area of decision making to their level of capacity [whether to receive an injection on the bed or in the playroom] may engage them positively in the treatment and satisfy a need for control.

4.2 The moral framework for adolescent decision making requires navigating between erroneously empowering children who are not yet morally prepared to make decisions and excluding children who are ethically and intellectually capable of making their own decisions.

The adolescent person presents a particular and peculiar set of quandaries for medical ethics considerations. On the one hand, from the age of 12 or 13 the literature documents that these teens have the ability to bring moral considerations to bear on decisions, have some notion of consequences that may follow from action, and have some experience that may be relevant to the actual decision contemplated. On the other hand, adolescents have fantasies of immortality, respond incommensurately to feelings and judgments of their peers, may be enmeshed in conflict with parents and authority figures, and may have less experience than is really required to weigh the risks and benefits of potentially compromising decisions.

Adolescents locked in age-appropriate combat with parents and physicians risk making potentially damaging health care decisions that may have long-standing negative consequences. Thus the parents, physicians, and teen, with welfare agencies and courts ready at hand, must create a tripartite structure that is able to reach decisions jointly.

The pediatric team is skilled at assessing the capabilities of the children they treat. Parents, who have their own hopes and fears, may be less so. Conflict between these groups is not common and is generally managed by the pediatric team over time. Very rarely it requires, as the new law recognizes, an intervention to manage, or hopefully, to resolve the conflict.

5. Clinical Ethics Consultation

5.1 Central to the task of the Clinical Ethics Consultation [CEC][16] is the matter of helping to bridge the natural power differentials that separate heath care staff and surrogates. Surrogates may be overwhelmed by the nature of the decisions that they are facing and by the generally foreign and intimidating culture, language, process and structure of the hospital. Surrogates need to be supported and empowered in order to be able to address the tasks presented to them.

In most instances, the surrogate and the medical team will review the options and will together reach a shared decision about what reflects the wishes and values of the patient or is in her best interest. At times, this communication will be at odds or fraught with conflict. At such junctures, a Clinical Ethics Consultation may be of help and the FHCDA recognizes this fact by incorporating reference to an ethics support mechanism under certain circumstances. Clinical Ethics Consultants can seek to clarify and address ethical concerns, defuse and disaggregate disagreement, and resolve conflict.

Clinical ethics consultation is an intervention in which a trained clinical ethics professional:

- responds in a timely fashion to the request for a CEC from any member of the medical care team, patient, or family member;
- reviews the patient's medical record;
- either interviews relevant medical stakeholders or gathers the clinical care team and other consultants to discuss the case;
- visits the patient and family whenever possible;
- as a preliminary matter, identifies the ethical issues at play and any sources of conflict;
- involves the patient or family with care providers to promote communication, explore options, and seek consensus, when appropriate;
- employs expert discussion of bioethical principles, practices, and norms and uses reason, facilitation, negotiation, or mediation to seek a common judgment regarding a plan of care going forward;
- attends to the social, psychological, and spiritual issues that are often at play in disagreements about the proper course of care;

- triggers a further process with hospital medical leaders or a bioethics committee to resolve the situation, if a resolution is not reached;
- follows up with a patient and family after the initial consultation (although this feature of CEC varies, since in some systems follow-up is a task solely for the medical team);
- records the process and substance of the consultation, including the consultant's recommendations and their justification, as part of the patient's medical record;
- reviews the consultation with others on the CEC service as a basic level of evaluation and peer review; and
- utilizes a formal and rigorous quality improvement process.[17]

The Clinical Ethics Consultation teams will be able to act as supports in circumstances where there are disagreements among the medical team and the surrogates. Clinical Ethics Consultation brings the skills of clarification, facilitation and mediation to what may appear, at first glance, to be intractable problems.

6. Conclusion

6.1 The FHCDA provides an extraordinary opportunity for health care institutions to create new supports for family members and other surrogate deciders. A doctor-surrogate relationship which is imbued with a notion of shared decision making demands that all of the obligations that are owed to the patient in regard to discussion, explanation, support and advice be provided to the surrogate.

Health care providers in NYS have long desired that family members be allowed to decide for the patient as the patient would have wanted or as an analysis of best interest would dictate. This new law permits and requires medical care providers to collaborate and share with surrogates in decisions about care.

Endnotes

1. In the Matter of Eichner and In the Matter of Storer, 52 N.Y.2d 363; 420 N.E.2d 64; 438 N.Y.S.2d 26 (1981); cert. denied, 454 U.S. 858, 102 S.Ct. 309 (1981).
2. *See* PHL 2994-d[4][a][i].
3. *See* PHL 2994-d[3][a][i].
4. *See* PHL 2994-d[3][c].
5. "Making treatment decisions has a negative emotional effect on at least one third of surrogates, which is often substantial and typically last months (or sometimes years). Future research should evaluate ways to reduce this burden, including methods to identify which treatment options are consistent with the patient's preferences." David Wendler and Annette Rid, *Systematic Review: The Effect on Surrogates of Making Treatment Decisions for Others*, Ann. Intern. Med. 2011, 154:336-346.
6. *See* PHL 2994-c[7].
7. *See* PHL 2994-a[5].
8. *See* PHL 2994-d[4][a][i].
9. *See* PHL 2994-d[4][a][ii].
10. *See id*.
11. Karp, Naomi and Wood, Erica, *Incapacitated and Alone: Health Care Decision-Making for the Unbefriended Elderly (ABA Commission on Law and Aging 2003)*, written by Ms. Karp and Ms. Wood with support from the Fan Fox and Leslie R. Samuels Foundation and in collaboration with the Samuel Sadin Institute on Law, Brookdale Center on Aging of Hunter College.
12. *See* PHL 2994-g[3].
13. *See* PHL 2994-g[4] & [5].
14. *See* PHL 2994-g[4].
15. *See* PHL 2994-g[5].
16. CEC is separate and is different from the statutorily required Ethics Review Committee.
17. Nancy Neveloff Dubler, Mayris P. Webber, Deborah M. Swiderski, and the Faculty and the National Working Group for the Clinical Ethics Credentialing Project, "Charting the Future: Credentialing, Privileging, Quality, and Evaluation in Clinical Ethics Consultation," Hastings Center Report 39, no. 6 (2009): 23-33.

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The Family Health Care Decisions Act and Human Subjects Research in New York State

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I. Introduction

The Family Health Care Decisions Act ("FHCDA")[1] fills a longstanding gap in New York law by establishing a framework to allow surrogates to make health care decisions for patients without consent capacity who have not otherwise provided instructions to direct their care. It provides an invaluable tool for surrogate decision-makers appointed pursuant to the FHCDA to honor the wishes of patients when they cannot speak for themselves, or to act in their best interests when their wishes are unknown. Prior to the passage of the FHCDA, families and close friends of patients did not have clear authority to make even routine health care decisions on behalf of their loved ones.

On its face, the FHCDA is intended only to provide standards and procedures for surrogate consent to health care decisions. However, much confusion has arisen about the nature and extent of the Act's impact on surrogate consent for medical research. While categorizing certain interventions properly as "treatment" or "research"—or both—is often difficult, the issue is further complicated by whether the protocol is controlled by federal or New York State law, which take different approaches to the authority of a health care surrogate to consent to participation in research on behalf of individuals lacking consent capacity. In addition to these legal issues, research involving this population also raises significant ethical concerns.

As a result of these complexities, the research policies that have predominated for the past several decades arguably have over-protected this population to the point of prohibiting virtually all research in which they would be necessary participants. While protection against unethical research is paramount, appropriate research that involves adults who are unable to provide first-person consent is essential to learn about and seek cures for the broad range of diseases and conditions that impair cognition.

This article explores the relationship between the FHCDA and surrogate consent to research.[2] It begins with a brief introduction to the salient differences between health care and research in order to frame the discussion of health care surrogates' authority to make decisions regarding research participation. After setting forth relevant New York State laws, the article suggests that the FHCDA arguably may allow surrogate consent to certain types of research conducted under New York law, but only where the intervention being studied truly can be considered health care.

The article goes on to assert that, while the FHCDA had a minimal (if any) impact on research governed by New York law, it had the collateral effect of greatly expanding surrogate consent to federally regulated research conducted in New York because of the federal policy allowing surrogates who have the authority to consent to an intervention for the purposes of health care (treatment) also to consent to that intervention for the purposes of research.

In light of the increased permissibility of research involving adults lacking consent capacity, the article closes with a recommendation for additional guidance from appropriate governmental bodies to ensure the consistent and ethical conduct of such research.

II. The Fine Line Between Treatment and Research

Appreciating the ethical and practical distinctions between clinical treatment and research is crucial to understanding the implications of permitting a health care surrogate to make decisions about research enrollment. The differences are reflected in both the professional relationship between the physician/researcher and the patient/participant, and the goals inherent in each endeavor.[3]

In the physician-patient relationship, care is tailored to the specific needs of the patient. In the researcher-participant relationship, interventions are prescribed according to a protocol and rarely may be altered to meet the needs of each individual. While physicians and researchers may engage in research to improve patient care, the primary goal of research is obtaining generalizable scientific information, such as safety and efficacy data, to benefit a class of patients. Only individualized medical care is administered with the goal of improving a particular patient's health.

This distinction is often difficult to discern when a protocol is classified as offering the prospect of direct benefit. In the research context, "direct benefit" refers to a positive therapeutic value related to a participant's health or welfare.[4] However, while individuals in clinical research may receive a therapeutic benefit from their participation, providing these benefits is not the *purpose* of the research.[5] Some commentators argue that usage of common scientific techniques, such as randomization, placebos, and double-

blind procedures, are incompatible with the principles of personalized clinical treatment.[6] Additionally, in certain direct benefit studies, the prospect of receiving the benefit may be very remote, and the benefit may not manifest in every participant. There also may be significant drawbacks to participation that outweigh the possible benefit. For example, participants may be asked to do a variety of things unrelated to the potentially beneficial intervention that are necessary to preserve the scientific integrity of the project, such as providing daily blood samples for the purpose of data gathering.

Research and treatment may overlap to the greatest degree in instances when a trial is done in "clinical equipoise"—*i.e.*, the genuine disagreement among expert clinicians about the relative merits of a certain investigational intervention as compared with the available alternatives.[7] But even in clinical equipoise, the "equipoise assessments are based on the expected benefits and burdens of the interventions for the overall patient population," rather than on particular individuals' unique characteristics, which may make them better suited for a particular arm of the study.[8] Therefore, characterizing a "direct benefit" study as "health care," even in instances of clinical equipoise, is not always accurate.[9]

Where jurisdictions do not have laws or regulations indicating which individuals may consent to research participation on behalf of someone who lacks consent capacity, researchers often turn to individuals who have been vested with authority to make health care decisions. Allowing health care surrogates to make research enrollment decisions may seem to be the best choice, particularly since those who qualify as health care decision-makers, such as spouses or siblings, likely would be the appropriate individuals to make decisions about research. However, some have questioned whether surrogates who have a distant or no prior relationship with a potential participant should make decisions regarding research enrollment, particularly where research presents no prospect of direct benefit. Moreover, in locales where surrogate decision making for health care is established, the legislature or appropriate governing body often has not explicitly considered whether health care surrogates should or could consent to research, and therefore the provisions attendant in health care laws often do not translate well into the research context. For example, issues such as how and when to assess a research participant's capacity or the criteria by which a surrogate should make research enrollment decisions may require additional considerations or alternative standards than those that are commonplace in the treatment context.[10] This leaves researchers and institutional review boards charged with reviewing protocols in the predicament of applying inappropriate health care standards to research protocols or using *ad hoc* research-specific rules.[11]

III. Law and Policy Governing Research with Adults Lacking Consent Capacity

A. New York: Public Health Law Article 24-A

Article 24-A of the Public Health Law governs the conduct of human subjects research in New York State. While Article 24-A applies to both publicly and privately funded research,[12] the Legislature expressly limited the applicability of Article 24-A to protocols that are not "subject to, [or] in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects."[13] Most research conducted in New York is either federally funded or otherwise subject to federal oversight, so Article 24-A applies only to the minority of research activity in the State.

Article 24-A defines "human research,"[14] provides mechanisms for obtaining informed consent, and establishes procedures for institutional oversight of human subjects research.[15] Although it does not provide many detailed rules for conducting research involving adults lacking consent capacity, Article 24-A clearly envisions that such research will take place. It defines "voluntary informed consent" as "the legally effective knowing consent of an individual *or his legally authorized representative*, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion."[16] In addition, the law states that, "[i]f the human subject be otherwise legally unable to render consent, such consent shall be subscribed to in writing *by such other person as may be legally empowered to act* on behalf of the human subject."[17] Finally, 24-A requires "the consent of the committee and the commissioner…with relation to the conduct of human subjects research involving minors, *incompetent persons, mentally disabled persons* and prisoners."[18]

While Article 24-A mentions "legally authorized representative" ("LAR") several times, it does not provide a definition of this term or hierarchy of individuals from which an LAR could be selected.[19] In addition, neither the legislative history of Article 24-A nor documents contemporary with its enactment shed light on whom the Legislature contemplated in this context, including whether a surrogate decision-maker in the health care or other contexts would qualify as an LAR. At the time of its passage, family members routinely served as surrogates for health care decisions,[20] and possibly for research participation decisions, but such authority was often informal. Given the paucity of laws governing health care decision making in existence during the time Article 24-A was proposed and enacted (1967-1975),[21] and that at that time, the concept of diminished consent capacity was usually focused on individuals with mental illness or those adjudged to be "incompetent," the Legislature may have been referring to certain Mental Hygiene laws that required a court to make

affirmative findings about a person's capacity and to appoint surrogate decision-makers.[22] Again, however, there is no evidence that the Legislature had any specific law in mind at the time of Article 24-A's passage.

To date, neither the Legislature nor New York State's Department of Health has specified the entities who would be considered "legally authorized" to consent to research on behalf of an adult lacking consent capacity.[23] Therefore, while conducting research pursuant to 24-A with individuals who lack consent capacity is arguably legal, the individuals who may consent to participation on behalf of this population was—and, continues to be—unclear.

B. New York: The FHCDA

Prior to the enactment of the FHCDA in 2010, New York law generally did not authorize surrogate decision making for health care on behalf of patients who lacked capacity unless a patient appointed a health care proxy when he or she had capacity, or was the subject of a guardianship proceeding.[24] The FHCDA filled this gap by creating a statutory framework for surrogate health care decision making where a patient lacks capacity,[25] including a hierarchy of individuals who can serve as surrogate decision-makers.[26] If prerequisites are met, the FHCDA authorizes surrogates to make decisions about "health care," which it defines as "any treatment, service, or procedure to diagnose or treat an individual's physical or mental condition."[27] The Act requires appointed surrogates to make patient-centered decisions based on the patient's wishes, or where his/her wishes are unknown, the patient's "best interests."[28]

The FHCDA was not drafted to govern surrogate consent to research, and its use in the research context was not expressly contemplated by the Legislature.[29] However, because of the overlap between health care and research, some have questioned the extent to which the FHCDA may authorize surrogates to consent to research participation on behalf of those lacking consent capacity.

At most, with respect to non-federally regulated research, the FHCDA might authorize surrogate decisions for enrollment in protocols that offer a prospect of direct benefit to the extent that it can be considered "health care" (as defined in the FHCDA), but likely does not allow for surrogate decision making to research that holds out any lesser prospect of direct benefit. This approach arguably preserves consistency with the purpose of a surrogate in the treatment context: to permit consent to interventions that represent either the wishes or the best interests of the individual, with the goal being to improve the patient's condition. It is important to note, though, that since neither the Legislature nor the Department of Health has spoken directly to this issue, caution may dictate following a conservative policy when considering whether to allow an FHCDA surrogate to make decisions regarding non-federally regulated research.

C. Federal Law and Policy

The Common Rule, which is the set of federal regulations that govern human subjects research, applies to research that is conducted, funded, or overseen by the federal government.[30] Among other things, the Common Rule prescribes the requirements for informed consent to research and the standards for approval and oversight of human subjects research protocols. It also mandates usage of "additional safeguards" to protect the rights and welfare of participants who are "likely to be vulnerable to coercion or undue influence," including "children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons."[31] The regulations include subparts delineating protections and safeguards for certain of these populations, namely children, pregnant women and fetuses/neonates, and prisoners.[32] However, the Common Rule does not have a similar subpart, or otherwise provide detail on appropriate "additional safeguards,"[33] for individuals who lack decision-making capacity.[34]

With respect to informed consent, the Common Rule provides that "no investigator may involve a human being as a subject in research…unless the investigator has obtained the legally effective informed consent of the subject *or the subject's legally authorized representative*."[35] Similar to Article 24-A, the federal regulations do not set a default hierarchy for selecting an LAR, but define LAR as "an individual or judicial or other body *authorized under applicable law* to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research."[36] This requirement has been interpreted to mean that the federal government will look to a state's formulation of LAR to determine which, if any, surrogates are authorized to consent to research conducted in that state. The federal government will recognize a state's definition of LAR if it is ensconced in statute, regulation, case law, or other legally binding authority;[37] however, non-binding guidelines are insufficient.[38] In states that do not provide a definition of or a standard for selecting an LAR, federally regulated research involving those who cannot provide informed consent arguably should not occur.

Importantly, federal policy does not require that a state set an LAR specifically for the purpose of research in order to allow the LAR to consent to research. Instead, where a state has authorized certain individuals to consent to an intervention for the purpose of treatment, federal policy will recognize that authority and allow those individuals to consent to the same intervention for the purpose of research.[39] Notably, federal policy does not explicitly

require that an intervention holds out the prospect of direct benefit to the participant—or even that the likelihood of benefit allows the intervention to be characterized as health care—in order for a health care surrogate to have the authority to consent to enrollment.[40] It is also unclear whether and to what extent federally regulated research requires adherence to parts of a state health care statute other than its surrogate hierarchy, such as the methods for determining capacity or the procedures for handling objections to determinations of incapacity or appointments of surrogates.[41]

D. The FHCDA's Effect on Federally Regulated Research Conducted in New York State

Because of the federal policy of importing health care decision-makers into the research context, the enactment of the FHCDA—a statute aimed at surrogate consent to health care—had the concomitant of vastly expanding the legality of surrogate-consent research in New York State.[42] While there are many advantages to allowing research that requires surrogate consent, including advancing scientific knowledge that could lead to treatments for illnesses that affect cognition, the dearth of rules and standards on either the federal or state level regarding the conduct of such research is problematic.[43] Although there is no evidence that any research is taking place in an unethical manner, a government-sanctioned system of safeguards and additional protections would ensure that research with adults who lack consent capacity proceeds in a consistent and ethically appropriate manner.

For the past two years, the New York State Task Force on Life and the Law has examined these issues and will release in the coming months a report evaluating legal and ethical dimensions of research involving adults lacking consent capacity.[44] The report will provide researchers and institutional review boards in New York with thorough guidance to assist them in the design, review and oversight of such research.

IV. Conclusion

The enactment of the FHCDA greatly enhanced the legality of surrogate consent to research involving adults lacking consent capacity, particularly with respect to federally regulated research. This development will permit potentially valuable scientific research into the unique illnesses and conditions that affect this population. However, simply authorizing health care surrogates to consent to research only allows the research to proceed—it does not provide necessary instruction on outstanding research-specific issues and questions. Further guidance in this area will promote consistency in research oversight and conduct, and encourage appropriate safeguards to ensure that the rights and welfare of research participants are optimally protected.

Endnotes

1. 2010 N.Y. Laws ch. 8.
2. This article does not address emergency research, research for which informed consent is waived, or research involving minors.
3. *See, e.g.*, NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT 4 (1979).
4. *Id.* at 8. In contrast, research seeking only to gain generalizable knowledge about the condition or treatment being studied is characterized as "no direct benefit" research.
5. Franklin G. Miller & Donald L. Rosenstein, *The Therapeutic Orientation to Clinical Trials*, 348 NEW ENG. J. MED. 1383, 1383 (2003).
6. Paul S. Appelbaum et al., *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 HASTINGS CTR. REPORT 20, 20 (1987).
7. Benjamin Freedman, *Equipoise and the Ethics of Clinical Research*, 317 NEW ENG. J. MED. 141, 144 (1987). Some commentators have argued that in instances of clinical equipoise, techniques such as randomization—where participants are randomly assigned to receive either the investigational intervention, the standard treatment, or possibly a placebo—do not pose additional harm to participants. Carl H. Coleman, *Research with Decisionally Incapacitated Human Subjects: An Argument for a Systemic Approach to Risk-Benefit Assessment*, 83 IND. L. J. 743, 752-53 (2008) [hereinafter Coleman, *Systemic Approach*] (discussing and critiquing these arguments).
8. Coleman, *Systemic Approach*, *supra* note 6, at 752-53.
9. Even when research participants are informed that any prospect of benefit is uncertain or nonexistent, studies show that they often mistakenly believe that they stand to benefit or they overestimate the likelihood that they will personally benefit. This phenomenon is known as the "therapeutic misconception." Charles W. Lidz & Paul S. Appelbaum, *The Therapeutic Misconception: Problems and Solutions*, 40 MED. CARE V-55, V-57–V-59 (2002).
10. For example, a health care statute requiring a surrogate to use a "best interest" standard when making a treatment decision arguably would not apply where a protocol holds out no prospect of direct benefit to the participant. Similarly, a law requiring lengthy capacity assessments by multiple practitioners may not be appropriate for research involving very low risk, such as observational gait studies.
11. Many commentators and ethicists have argued that the differences between treatment and research warrants distinct ethical analyses. *See*, *e.g.*, Franklin G. Miller & Howard Brody, *A Critique of Clinical Equipoise: Therapeutic Misconception in the Ethics of Clinical Trials*, 33 HASTINGS CTR. REPORT 19, 20 (2003).
12. N.Y. Pub. Health Law § 2444 (2011) (requiring "[e]ach public or private institution or agency which conducts…human research… [to] establish a human research review committee," the State equivalent of an Institutional Review Board (IRB)).
13. *Id.* § 2445. Research is subject to federal oversight when it is: (1) federally funded; (2) conducted on drugs, devices or other products that fall within the jurisdiction of the Federal Food and Drug Administration (FDA), and therefore must comply with its applicable rules and regulations, *see generally* 21 C.F.R. pts. 50, 56 (2011) (governing human subjects research); or (3) conducted pursuant to a "Federalwide Assurance for the Protection of Human Subjects," a document filed by an institution with the federal government that provides that all human subject research activities at that institution, regardless funding source, will comply with the federal research protections provided in the Common Rule (45 C.F.R. pt. 46 (2011)). *See* Office of Human Research Protections ("OHRP"), Human Research Protections Frequently Asked Questions, *What Compliance Assurance Process for Human Subject Protection is Accepted by the Office for Human Research Protections*

and other Federal Agencies?, http://answers.hhs.gov/ohrp/categories/1563 (last visited Jan. 29, 2011); *see generally* Carl H. Coleman et al., *The Ethics and Regulation of Research with Human Subjects*, 161 (Lexis/Nexis 2005).

14. Interestingly, the definition of "human research" under Article 24-A is somewhat narrower than the definition of "human subjects research" under federal regulations. *Compare* N.Y. Pub. Health Law § 2441(2) with 45 C.F.R. § 46.102(d).
15. *See generally* N.Y. Pub. Health Law §§ 2440-46.
16. *Id.* § 2441(5) (emphasis added).
17. *Id.* § 2442 (emphasis added).
18. *Id.* § 2444(2) (emphasis added).
19. Some states have passed legislation that specifically addresses and authorizes certain surrogates to consent to research. *See, e.g.*, Cal. Health & Safety Code § 24178 (2010) (California); Va. Code Ann. § 32.1-162.18 (2010) (Virginia); N.J. Stat. Ann. § 26:14-5 (2011) (New Jersey); *see also* John M. Luce, *California's New Law Allowing Surrogate Consent for Clinical Research Involving Subjects with Impaired Decision-Making Capacity*, 29 INTENSIVE CARE MED. 1024, 1025 (2003); Elyn R. Saks et al., *Proxy Consent to Research: The Legal Landscape*, 8 YALE J. HEALTH POL'Y L. & ETHICS 37, 44-45 (2008) [hereinafter Saks et al., *Proxy Consent to Research*].
20. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, WHEN OTHERS MUST CHOOSE: DECIDING FOR PATIENTS WITHOUT CAPACITY 28 (1992).
21. Article 24-A's enactment in 1975 pre-dates the Health Care Proxy statute, N.Y. Pub. Health Law art. 29-C (2011) (effective 1991); the Health Care Decisions Act for Persons with Mental Retardation/Developmental Disabilities, N.Y. Surr. Ct. Proc. Act § 1750-b (2011) (effective 2002); the current Guardianship statute, N.Y. Mental Hyg. Law art. 81 (2011) (effective 1993); the Surrogate Decision-Making Committee statute, N.Y. Mental Hyg. Law art. 80 (2011) (effective 1986); and the Do Not Resuscitate ("DNR") laws, N.Y. Pub. Health Law Art. 29-B (2011) (effective 1988) and art. 29-CCC (2011) (effective 2010). Although the Durable Power of Attorney statute, which was enacted prior to 1975, allows for some health care decision making, this authority was construed by a 1984 Attorney General Opinion as narrow. *See* N.Y. Gen. Oblig. Law § 5-1501 (effective 1964); *see also* 1984 Op. N.Y. Att'y Gen. 58 (No. 84-F16) ("A durable power of attorney may not be used to delegate to an agent generally the authority to make health care decisions on behalf of an incompetent principal. However, a durable power of attorney may be used to delegate specifically to an agent the responsibility to communicate the principal's decision to decline medical treatment under defined circumstances.").
22. *See* N.Y. Mental Hyg. Law art. 77, *repealed by* N.Y. Mental Hyg. Law art. 81 (2011) (effective 1993); N.Y. Mental Hyg. Law art. 78, *repealed by* N.Y. Mental Hyg. Law art. 81 (effective 1993); *see also* Pub. Health Law § 2803-c (3)(j). Specifically, former Mental Hygiene Article 78 allowed courts to appoint a "committee of the person" or a "committee of the property" upon a finding of incompetence. N.Y. Mental Hyg. Law art. 78, *repealed by* N.Y. Mental Hyg. Law Art. 81. Similarly, former Article 77 allowed courts to appoint conservators upon a finding by clear and convincing evidence that a person was unable to manage their affairs. N.Y. Mental Hyg. Law art. 77 (governing appointments of conservators), *repealed by* N.Y. Mental Hyg. Law art. 81. While Article 77 was intended to bestow only powers over the conservatee's property and associated decisions, over time, it was amended and interpreted to encompass personal decisions as well. *See* Dale L. Moore, *The Durable Power of Attorney as an Alternative to the Improper Use of Conservatorship for Health-Care Decisionmaking*, 60 ST. JOHN'S L. REV. 631, 642 (1986). *But see In re Grinker*, 77 N.Y.2d. 703 (1991) (invalidating this interpretation and finding that a conservator did not have the power to make the personal decision to place a conservatee in a nursing home).
23. This is not to suggest that the Department of Health has never attempted to address the concept of surrogate consent to research. Among other efforts, the Department commissioned an advisory work group to study the issue, which released a draft report for public comment in 1999. *See* DEPARTMENT OF HEALTH ADVISORY WORK GROUP ON HUMAN SUBJECT RESEARCH INVOLVING PROTECTED CLASSES, RECOMMENDATIONS ON THE OVERSIGHT OF HUMAN SUBJECT RESEARCH INVOLVING PROTECTED CLASSES (1999); *see also* AD HOC WORKGROUP CONVENED BY THE NEW YORK ACADEMY OF MEDICINE, CONSENT FOR RESEARCH WITH DECISIONALLY INCAPACITATED ADULTS (2004). Additionally, the New York State Office of Mental Health promulgated regulations in 1990 governing research with the adults lacking consent capacity, but they were struck down on the basis that only the Commissioner of Health was provided with the authority to promulgate regulations under Article 24-A. *T.D. v. N. Y. State Office of Mental Health*, 165 Misc.2d 62, 73 (N.Y. Sup. Ct. 1995), *aff'd* 228 A.D.2d 95 (N.Y. App. Div. 1996), *aff'd in part, rev'd in part*, 91 N.Y.2d 860 (1997). *But see* 14 N.Y. Comp. Codes R. & Regs. tit. 14, § 27.10 (2011) (effective 1975).
24. More specifically, New York law provided for surrogate decision making for health care for three main categories of incapable adult patients: (i) patients who had previously appointed a health care agent pursuant to New York's Health Care Proxy Law, *see* N.Y. Pub. Health Law art. 29-C; (ii) persons who had a court–appointed guardian under Mental Hygiene Law Article 81, provided the guardianship order conveyed health care decision-making authority, *see* N.Y. Mental Hyg. Law § 81.22 (8); and (iii) persons with mental retardation or developmental disabilities who had a court-appointed guardian under Surrogate Court Procedure Act Article 17-A. *See* N.Y. Surr. Ct. Proc. Act § 1750-b. New York also has other surrogate decision-making laws for specific categories of health care decisions. *See, e.g.*, N.Y. Pub. Health Law art. 29-B (applicable to decisions about cardiopulmonary resuscitation); N.Y. Pub. Health Law § 4301(2) (governing anatomical gifts).
25. *See supra* note 1; *see generally*, Robert N. Swidler, *New York's Family Health Care Decisions Act: The Legal and Political Background, Key Provisions and Emerging Issues*, 82 N.Y. St. B. Ass'n J. 18 (June 2010). The FHCDA applies only to decisions made about care in "general hospitals" and "residential health care facilities." *See* N.Y. Pub. Health Law § 2994-a(18) (2011); *see also id.* § 2994-b. A recent recommendation by the Task Force on Life and the Law suggested that the Legislature expand the FHCDA to decisions made about hospice care. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, RECOMMENDATIONS REGARDING THE EXTENSION OF THE FAMILY HEALTH CARE DECISIONS ACT TO INCLUDE HOSPICE (2010), http://www.health.state.ny.us/regulations/task_force/docs/2010-1130_recommendations_regarding_the_extension_of_family_health_care_decisions_act.pdf (last visited Feb. 10, 2011). For more information about the Task Force, please see http://www.health.state.ny.us/nysdoh/taskfce/.
26. N.Y. Pub. Health Law § 2994-d(1).
27. *Id.* § 2994-a(12); *see also id.* § 2994-a(14) (defining "health care decision").
28. *Id.* § 2994-d(4)(a)(ii). When determining a patient's best interests, the FHCDA instructs surrogates to consider "the dignity and uniqueness of every person; the possibility and extent of preserving the patient's life; the preservation, improvement or restoration of the patient's health or functioning; the relief of the patient's suffering; and any medical condition and such other concerns and values as a reasonable person in the patient's circumstances would wish to consider." *Id.*
29. The FHCDA does not refer to "research" or to Article 24-A.
30. The Common Rule was promulgated by the Department of Health and Human Services ("HHS") and has been adopted by seventeen government agencies in order to promote uniformity in the conduct of federally regulated human subjects research. *See generally* 45

C.F.R. pt. 46; 21 C.F.R. pts. 50, 56 (corresponding FDA regulations). Human subjects research is primarily overseen by the Office for Human Research Protections (OHRP), which provides guidance for its conduct and ensures regulatory compliance.

31. 45 C.F.R. § 46.111(b).

32. *See generally* 45 C.F.R. §§ 46.201-.207 (pregnant women, fetuses, and neonates), 46.301-.306 (prisoners), 46.401-.409 (children).

33. However, examples of some additional safeguards that the federal government has deemed acceptable for individuals who lack decision-making capacity can be found in OHRP determination letters. *See e.g.*, Letter from Dr. Michael A. Carome, Dir. of Div. of Compliance Oversight, OHRP, to John M. Allen, Assistant Vice President for Scientific Affairs, Health Sci. Ctr. at State Univ. N.Y. Downstate Med'l Ctr. & John O'Hara, Research Found. Campus Operations, Health Sci. Ctr. at State Univ. N.Y./Downstate Med. Ctr. (Apr. 17, 2002), http://www.hhs.gov/ohrp/detrm_letrs/YR02/apr02r.pdf (last visited Feb. 15, 2011) (citing with approval the use of independent consent monitors, subject advocates, and special education techniques as additional safeguards for research with potentially vulnerable populations).

34. In 2006, OHRP convened a subcommittee of its Secretary's Advisory Committee on Human Research Protections ("SACHRP") to address the lack of guidance addressing research with adults lacking consent capacity. Known as the Subcommittee on the Inclusion of Individuals with Impaired Decision-Making in Research ("SIIIDR"), its charge was to "develop recommendations for consideration by SACHRP about whether guidance and/or additional regulations are needed for research involving individuals with impaired decision-making capacity." SIIIDR made ten recommendations that included a request for guidance on matters such as additional safeguards for research pursuant to 45 C.F.R. § 46.111, the selection and responsibilities of LARs, as well as a call for a new subpart to the Common Rule that would include a default federal LAR hierarchy that could be used in the absence of applicable state law. SACHRP, RECOMMENDATIONS FROM THE SUBCOMMITTEE FOR THE INCLUSION OF INDIVIDUALS WITH IMPAIRED DECISION MAKING IN RESEARCH (SIIIDR), http://www.hhs.gov/ohrp/sachrp/20090715letterattach.html (last visited Feb. 15, 2011) [hereinafter SIIIDR RECOMMENDATIONS]. SIIIDR forwarded to these recommendations to the Secretary of HHS in 2009, but HHS has not taken any official action on them to date. *See* Letter from SACHRP, Advisory Comm. to OHRP, to the Hon. Kathleen Sebelius, Sec'y of HHS (Mar. 24, 2010), http://www.hhs.gov/ohrp/sachrp/20090715lettertohhssecretary.html (last visited Jan. 14, 2011). The National Institutes of Health ("NIH") also released a document addressing issues similar to those addressed by SIIIDR. NAT'L INST. OF HEALTH RESEARCH INVOLVING INDIVIDUALS WITH QUESTIONABLE CAPACITY TO CONSENT: NIH POINTS TO CONSIDER (2009), http://grants.nih.gov/grants/policy/questionablecapacity.htm (last visited Feb. 10, 2011) [hereinafter NIH POINTS TO CONSIDER].

35. 45 C.F.R. § 46.116 (emphasis added).

36. *Id.* § 46.102 (emphasis added).

37. OHRP, Human Research Protections Frequently Asked Questions, *Who Can be a Legally Authorized Representative (LAR) for the Purpose of Providing Consent on Behalf of a Prospective Subject?*, http://www.hhs.gov/ohrp/informconsfaq.html (last visited Jan. 30, 2011) [hereinafter OHRP, LAR FAQ]; *see also* Letter from Dr. Kristina C. Borror, Compliance Oversight Coordinator, OHRP, to Dr. Donald C. Harrison, Senior Vice President and Provost for Health Affairs, Univ. of Cincinnati & Dr. Elliot G. Cohen, Senior Executive Officer, Univ. Hosp., Inc. et al. (Feb. 5, 2002), http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02i.pdf (last visited Jan. 29, 2011); Letter from Robert J. Meyer, Compliance Oversight Coordinator, OHRP, to Dr. Donald E. Wilson, Dean, Sch. of Med., Univ. of Md., Baltimore (Feb. 4, 2002), http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02f.pdf (last visited Feb. 10, 2011).

38. OHRP has also made clear that institutional guidelines alone cannot provide a basis for determining who may serve as an LAR in the absence of state law. *See* Letter from Dr. Kristina C. Borror, Compliance Oversight Coordinator, OHRP, to Dr. Nathan Kase, Interim Dean, Mount Sinai Sch. of Med. (May 7, 2002), http://www.hhs.gov/ohrp/detrm_letrs/YR02/may02a.pdf (last visited Feb. 15, 2011); *see also* SIIIDR RECOMMENDATIONS, *supra* note 34, at 13.

39. *See* 45 C.F.R. § 46.102(c); *see also* OHRP, LAR FAQ, *supra* note 37; *see also* Letter from Carol J. Weil, Division of Compliance Oversight, OHRP, to Dr. Fawaz T. Ulaby, Vice President for Research, Univ. of Mich., Ann Arbor (Feb. 11, 2002), http://www.hhs.gov/ohrp/detrm_letrs/YR02/feb02n.pdf (last visited Feb. 15, 2011) (acknowledging the university's reliance on applicable statute to authorize surrogate consent to research); Saks et al., *Proxy Consent to Research*, *supra* note 19 at 52.

40. *See* 45 C.F.R. § 46.102; *see also* OHRP, LAR FAQ, *supra* note 37. *But see* Letter from Robert J. Meyer, Compliance Oversight Coordinator, OHRP, to Dr. Regis B. Kelly, Executive Vice Chancellor, Univ. of Ca. S.F. (Apr. 11, 2002), http://www.hhs.gov/ohrp/detrm_letrs/YR02/apr02p.pdf (last visited Feb. 15, 2011) (noting with approval that the institution applied state laws governing surrogate consent to health care because the study was comparing two forms of "accepted medical treatment").

41. *See* N.Y. Pub. Health Law § 2994-c(6); *see also* Coleman, *Systemic Approach*, *supra* note 6, at 760 (recognizing that the federal regulations are "silent on the substantive standards" an LAR must apply). However, a state could, through applicable law such as legislation, regulation or case law, impose additional requirements with respect to participation in federally regulated research within that state's borders. *See, e.g.*, Cal. Health & Safety Code § 24178 (2011); N.J. Stat. Ann. §§ 26:14-5 (2011).

42. *See, e.g.,* Letter from Dr. Kristina C. Borror to Dr. Nathan Kase, *supra* note 38 (cautioning a New York institution prior to the enactment of the FHCDA to "ensure that there is a sound legal basis under applicable New York State law" permitting surrogate consent to research). Several New York institutions revised their policies to allow for surrogate consent to research after the FHCDA was passed.

43. *But see generally* SIIIDR RECOMMENDATIONS, *supra* note 32; NIH POINTS TO CONSIDER, *supra* note 34.

44. The Task Force is an interdisciplinary committee of 22 governor-appointed experts, charged with making policy recommendations on issues arising at the intersection of law, medicine and ethics. For more information about the Task Force, please see http://www.health.ny.gov/regulations/task_force/.

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A Bridge for People with Developmental Disabilities: The FHCDA and HCDAPMR Need Some Reconciliation

By Paul R. Kietzman

Several years before New York adopted the Family Health Care Decisions Act (FHCDA), it adopted a surrogate decision-making law for persons with intellectual disabilities, the Health Care Decisions Act for Persons with Mental Retardation (HCDAPMR).[1] As undeveloped and inadequate as the statutory end-of-life law of New York was for persons without intellectual disabilities, the Courts and ultimately the legislature acknowledged in the passage of HCDAPMR that the law of this State was a particular hardship on its citizens with intellectual and other developmental disabilities ("ID/DD").[2]

Subsequent to its enactment in 2003, the HCDAPMR was widely and successfully implemented across the State's system of care overseen by the Office for People With Developmental Disabilities (OPWDD), but not without broad legal challenges to its constitutionality and purported retroactivity as to guardians appointed prior to its effective date.[3] The statute was incrementally amended to confer end-of-life decision-making authority to corporate guardians, to guardians of persons with developmental disabilities, to "qualified" family members of persons with ID/DD who had no appointed guardian, and ultimately to add the Willowbrook Consumer Advisory Board and Surrogate Decision-Making Committees[4] to the list of non-guardian surrogates who could consent to the withholding/withdrawal of life-sustaining treatment. NYSARC, as Article 17-A primary corporate guardian for well over 300 individuals and as residential service provider for tens of thousands of aging persons with ID/DD, uses this statutory scheme on a weekly basis.

As the window of opportunity for passage of the FHCDA opened a crack in the Spring of 2010, there was a great deal of give and take among the legislative committee chairs, their staff, and advocates and service providers of all persuasions, including NYSARC, over the issue of how the statute would deal with health care decisions for persons with ID/DD. Having mid-wifed and wet nursed the SCPA 1750-b, NYSARC was vigilant for any traces of baby in the FHCDA bathwater. The outcome of that final dialogue was largely satisfactory to the ID/DD advocacy community, with a few exceptions, which will be the subject matter of this article.

There is much to like about the FHCDA, most notably for the OPWDD provider and advocacy community the fact that SCPA 1750-b, as well as the OPWDD medical consent,[5] health care proxy,[6] and perhaps other related regulations were preserved.[7] It is not clear to me that the OPWDD DNR regulations survive at this point.[8] Hospital and nursing home patients with a diagnosis of ID/DD, patients with a history of OPWDD services, or patients admitted from an OPWDD system facility will have health care decisions, which they might currently lack capacity to make themselves, made pursuant to familiar statutory and regulatory processes, including SDMCs. Also, a new definition of "life-sustaining treatment" was added by the FHCDA to the HCDAPMR,[9] so that the authority of guardians and other surrogates to make end-of-life decisions now includes decisions to forgo cardiopulmonary resuscitation.

In recognition of the legislature's unique opportunity to enact the FHCDA after more or less twenty years of effort, some unresolved matters relating to the Mental Hygiene system of care were referred to a special committee of the Governor's Task Force on Life and the Law,[10] which as of this writing has not been formally constituted. Other matters seem to have simply gotten lost in the midst of twenty years of drafting, negotiating and re-drafting.

In addition to the new and expanded SCPA definition of life-sustaining treatment in SCPA 1750-b, the bill made some major modifications to Public Health Law Article 29-B, which had, since its enactment in 1987, addressed "orders not to resuscitate" in a broad range of facilities including general hospitals, nursing homes, psychiatric centers and "schools" listed in Mental Hygiene Law 13.17.[11] The FHCDA created a new PHL Article 29-CC ("Nonhospital Orders Not To Resuscitate"), which, at new section 2994-cc 5, states that consent by a patient or by a surrogate of a resident of a "mental hygiene facility" shall be governed by newly amended PHL article 29-B.[12] However, the amended definition of "hospital" in the new PHL article 29-B is outdated in referring to "school(s) named in section 13.17 of the mental hygiene law." The term "attending physician" was re-defined as a physician selected by or assigned to a "patient in a hospital." More to the point, there were and are no "schools" named in MHL 13.17 at the time of FHCDA enactment, and even interpreting intent in some uncomfortably broad way, all of MHL article 13 applies only to State-run facilities. Residential facilities operated by private non-profit providers like NYSARC presently serve significantly larger numbers of ID/DD New Yorkers than State facilities.

Also, any person presently or previously served in the OPWDD care system (State-operated or voluntary operated) would be eligible for end-of-life decision making under SCPA 1750-b, which now includes DNRs. There was no reason for the amended PHL Article 29-B to address any need of OPWDD consumers, and, I believe, the OMH provider and advocacy community agrees that the Article should be repealed and/or replaced. However, the purpose of this piece is to argue that before the work of the Governor's Task Force results in…whatever it results in, there is a need for a few matters (as to which there is believed to be no significant disagreement) to be resolved. I would start with the repeal of PHL Article 29-B, and a nip and a tuck to the other involved statutes.

What's to like about SCPA 1750-b? In the first place it more than survived its trip through the appellate courts of the State. Justice Graffeo, writing for the Court of Appeals in *Matter of MB*,[13] affirming the basic constitutionality and retroactive effect of SCPA 1750-b, stated:

> In the wake of *Storar*, a distinction arose between the common-law rights of competent adults, who could make their wishes concerning end-of-life care known to family and friends, and mentally retarded persons who had never been competent to make their own health care decisions and for whom life-sustaining treatment could not be refused. When these mentally retarded individuals became irreversibly, terminally ill they were, in effect, ineligible for hospice or other palliative care because their guardians were unable to refuse more intrusive, acute medical treatments aimed at extending life for as long as possible.

This was the situation the Legislature sought to remedy when it enacted the Health Care Decisions Act for Persons with Mental Retardation (HCDA).…"

In this technically moot case (MB died while the matter was before the Staten Island Surrogate), the Court of Appeals went on to note approvingly that the 1750-b process, among other things, requires: that the guardian/surrogate "advocate for the full and efficacious provision of health care, including life-sustaining treatment";[14] a de novo two physician certification of the person's lack of capacity to make the end-of-life decision at hand;[15] as well as providing a "…notification and objection process…[which]…provides substantial protection to mentally retarded patients."[16]

Among the entities entitled to both object to and seek administrative and judicial review of a guardian or other surrogate decision are the Mental Hygiene Legal Service (MHLS) for persons served residentially in the OPWDD system, OPWDD itself where a person is not currently residentially served in its system, and State and private (like NYSARC) providers of residential services to the patient. The responsibilities of MHLS to advocate broadly for persons with ID/DD are set forth succinctly in statute at MHL Article 47. The duty of the OPWDD service provider is more subtly spread throughout the MHL.[17] Probably the clearest demonstration of the obligations of OPWDD facility directors is found in the very framework of the *Storar* decision referenced in *Matter of MB*.[18]

As the dissenters in *Storar* accurately put it: "(u)ntil today, however, this court has never recognized the standing of a medical care provider to seek authorization to continue medical care against the wishes of a patient or one who stands in his stead."[19]

In 1986, when the Legislature undertook the enactment of the former PHL Article 29-B it could have ignored the *Storar* majority's finding that "the peculiar facts of this case" justified not only the filing of the petition but the continued party participation by Director Soper through all three Courts. Instead, it embraced that right/duty in numerous sections of Article 29-B,[20] conferring a plethora of rights concerning notification, objection, and the seeking of administrative and judicial review of surrogate DNR decisions. Arguably, these directors, generally entrusted with the life-long care of their residents, can be said to be exercising the State's *parens patriae* power in this statutory scheme.

Among the things that remain troubling about the FHCDA-amended PHL Article 29-B is the removal of virtually all rights of facility directors which formerly existed in the sections enumerated above.[21] SCPA 1750-b recognizes at all stages of the decision-making process that the State (through OPWDD facility directors and MHLS) as well as non-profit facility directors, like NYSARC's, have the right to be informed and to object to matters of both substance and process as to each end-of-life decision.

Also, assuming that PHL Article 29-B can't apply to persons with ID/DD outside State facilities (if at all…), the "presumption in favor of resuscitation"[22] no longer applies to anyone anywhere under the FHCDA, except as the presumption is embodied in the guardian's duty to "advocate."[23] Bear in mind that SCPA 1750-b applies regardless of setting—even in three-bed rural community homes. Whatever caused the legislature to abandon the presumption in new PHL Articles 29-C and 29-CC, the State's long, unhappy history of patients with ID/DD being under-treated militates in favor of the presumption in 1750-b 4.

A few other more mechanical problems arise under the FHCDA. As currently formulated the HCDAPMR[24] refers objecting parties to hospital "dispute mediation system(s)" established pursuant to PHL section 2972 (part of Article 29-B). Since the definition of hospital in 2961 9, no longer means "general hospital" or nursing home, the appropriate reference in the HCDAPMR[25] should be to "ethics review committee(s)" established pursuant to new PHL 2994-m.

Probably the most common basis for the entry of a DNR for a person with ID/DD is that CPR would be "medically futile"[26]—that "cardiopulmonary resuscitation will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest (sic) in a short time period before death occurs." That finding, "to a reasonable degree of medical certainty," by a physician who has personally examined a patient will in and of itself suffice as a basis for a DNR. That standard was not embodied anywhere in SCPA 1750-b by the FHCDA. It should be borrowed from PHL Article 29-B and inserted both in PHL Article 29-C and in the HCDAPMR.[27]

These and a minimal number of other minor language tweaks to SCPA 1750-b would, it is submitted, put the application of the FHCDA to patients with ID/DD on a firmer, clearer foundation while we await the work of the Governor's Task Force on Life and the Law. A bill containing these provisions is drafted and being shared with appropriate NYSBA committees, legislators and staff, other stakeholders, and the GTFLL staff.

Endnotes

1. Surrogate's Court Procedures Act section 1750-b, which became part of SCPA Article 17-A, "Guardians of Mentally Retarded and Developmentally Disabled Persons, SCPA sections 1750 through 1761."
2. The term "mental retardation" is being incrementally stricken from the lexicon.
3. *See Matter of MB*, 6 NY3d 437 (2006).
4. "SDMCs"—*see* Mental Hygiene Law, Article 80.
5. 14 NYCRR 33.11.
6. 14 NYCRR 633.20.
7. *See* Public Health Law section 2994-b, subsection 3.
8. *See* 14 NYCRR 633.18.
9. SCPA 1750-b 4.
10. *See* FHCDA, L.2010, Ch. 8, section 28.
11. PHL Article 29-B is now called "Orders Not to Resuscitate for Residents of Mental Hygiene Facilities."
12. Mental hygiene facility is appropriately defined in new PHL 2994-aa 12 as a residential facility "operated or licensed by" OMH or OPWDD.
13. *Supra* note 3, 6 NY3d at 439.
14. 6 NY3d at 442, quoting from SCPA 1750-b 4.
15. 6 NY3d at 451.
16. *Id.* at 454.
17. *But see* MHL Article 33, and, in particular, sections 33.01 and 33.03 (b) 4, requiring facility directors to ensure the obtaining of informed consent for surgery or other major medical treatment.
18. *Matter of Storar*, 52 NY 2d 363 (1981), another technically moot case that the Court of Appeals elected to hear because of the significance of the legal subject matter.
19. 52 NY 2d at 388. John Storar's mother was his SCPA 17-A guardian, and it was her difficult decision to deny her son blood transfusions that was overridden by the courts, on the petition of the State's facility director, Charles Soper, who expressly relied upon his "duty" under MHL 33.03.
20. Including subsections 2964 4, 2965 4(c), 2966 2, 2972 2, and 2973 1.
21. *See* FHCDA L.2010, Ch. 8, sections 12, 14, 18 and 19, e.g.
22. The partial title of PHL 2962.
23. Found in SCPA 1750-b 4, quoted fully in the *MB* decision, *supra*.
24. SCPA 1750-b 5(d).
25. *Id.*
26. As that term is defined in PHL Article 29-B at 2961 12.
27. SCPA 1750-b 4(b)(i).

Paul R. Kietzman is General Counsel to NYSARC, Inc., and previously was General Counsel to the NYS Office of Mental Retardation and Developmental Disabilities (now the NYS Office for People With Developmental Disabilities). This article was prepared and submitted with the knowledge and approval of NYSARC leadership, but the views expressed are those of the author, and not necessarily those of NYSARC. NYSARC, Inc., New York State's largest provider of services to persons with intellectual and other developmental disabilities, serves over 60,000 persons daily.

Surrogate Decision Making for Incapable Adult Patients with Mental Disabilities: A Chart of Applicable Laws and Regulations[1]

By Robert N. Swidler

Introduction

The Family Health Care Decisions Act governs health care decisions for patients in hospitals or nursing homes who lack capacity and who did not previously appoint a health care agent. However, a section in the FHCDA identifies circumstances where decisions for adult patients with mental disabilities are governed by laws or regulations other than the FHCDA, specifically NY Surrogate Court Procedure Act Article 17-A (the Health Care Decisions Act for People with Developmental Disabilities), MHL Article 80 (Surrogate Decision Making Committees), or OPWDD or OMH surrogate decision-making regulations.[2]

The following two charts are intended to help hospitals and nursing homes identify the applicable decision-maker, and the applicable law or regulation, for consent to treatment, or to withdraw or withhold life-sustaining treatment, for adult hospital and nursing home patients with mental disabilities in different circumstances. There is a chart for patients with developmental disabilities, and a chart for patients with mental illness.

During Nov. 2010 - Jan. 2011, Greater New York Hospital Association convened a group that reviewed and proposed corrections and improvements to an earlier version of these charts.[3] Eileen Zibell, Associate Attorney for OPWDD, John Tauriello, Counsel to OMH, and John Carroll, Deputy Counsel to OMH, also participated in that review, and suggested edits to the charts. This revised version is the product of that review.

A few caveats:

- These charts reflect only the views of the author.
- These charts do not reflect the official guidance of any state agency.
- Some of these issues are not clearly resolved, or are subject to conflicting interpretations.
- These charts point to the applicable laws and regulations and the decision maker, but do not summarize other requir-ments or conditions relating to such decisions.
- Ultimately, users must rely upon the language of the applicable laws and regulations, and any official guidance provided by the applicable agency. These charts are not a substitute for legal advice.

Even with those caveats, these charts should be useful. Please direct any corrections, suggestions to swidlerr@nehealth.com.

The Need for Reform

The charts describe what the law is, not what it should be. But it is difficult to examine these charts without recognizing a need for reform. Indeed, the very fact that there is a need for complex charts like these to navigate among multiple laws and regulations reveals a pressing need for simplification, such as through the consolidation, elimination, or reconciliation of some of these laws and regulations. The Legislature, when it enacted the FHCDA, anticipated this need and directed the NYS Task Force on Life and Law to form a special subcommittee to consider extending the FHCDA to cover life-sustaining decisions for persons with mental disabilities, thereby replacing at least some other laws and regulations. L.2010, ch.8, § 28.1.

But the charts also reveal other specific problems and anomalies that could be addressed more promptly, without waiting for or intruding upon the Task Force's assignment. In this author's view, the following steps would help reduce confusion, and improve decision making for persons with mental disabilities:

1. Amend SCPA §1750-b to confirm that a surrogate decision is not necessary if the developmentally disabled person made a prior oral or written decision, or appointed a health care agent, and had capacity at the time. (This would confirm Chart 1 boxes 1B and 2B).
2. Amend 14 NYCRR §633.10(a)(7)(iv)(c) to include domestic partner or close friend on OPWDD's surrogate priority list. (This would affect Chart 1 boxes 4B and 6B).

3. Amend the FHCDA to make the MHL Art. 80 surrogate decision-making committee (SDMC) available as an optional alternative to securing a decision pursuant to the FHCDA, as opposed to the required decision-maker. (This would affect Chart 1 boxes 5A and 5B).

4. Amend SCPA §1750-b to allow a DNR order to be entered based on medical futility for a patient who does not have a family member or friend to act as surrogate, eliminating the need to SDMC approval of such cases. (This would affect Chart 1 box 5B).

5. Repeal PHL Article 28-B, the DNR Law for patients of mental hygiene facilities, because there is no need for the law. For patients in OPWDD facilities, DNR orders generally are issued pursuant to SCPA §1750-b, not PHL Art. 29-B. For patients in psychiatric hospitals and general hospital psychiatric units, DNR orders should be made subject to the FHCDA—a change that would eliminate the confusion and illogic of inconsistent DNR procedures within general hospitals that have psychiatric units. (This would confirm Chart 1 boxes 6B and 7B, and affect Chart 2 boxes 6B and 7B).

6. Amend SCPA §1750 to restore role of MHLS with respect to DNR orders to what it was under the former DNR Law: for patients who are in or transferred from a mental hygiene facility, notice of a DNR order went to the mental hygiene facility director, not to MHLS; and the order would be temporarily stayed if there was an objection by the facility director, not by MHLS. As an alternative, require notice of DNR orders to MHLS but provide that its objection will not cause a stay of the DNR order unless it sets forth a specific basis for asserting that the DNR order is improper. (This would affect the procedures within Chart 1 column B rows 3-7).

A final note: If the Legislature adopts amendments that impact these charts, revised charts will be placed on the NYSBA Family Health Care Decisions Act Information Center website, www.nysba.org/fhcda.

Surrogate Decision Making for Incapable Adult Patients with Developmental Disabilities:

A Chart of Applicable Laws and Regulations

	Follow the rules in the first row that applies:	Decisions in Hospitals and Nursing Homes	
		A **Consent to treatment**	**B** **Decision to withdraw or withhold life-sustaining treatment (including entering a DNR Order)**
1	**Patient, previously when capable, left prior written or oral directions**	Follow patient's prior oral or written directions[4]	Follow: (i) patient's prior written directions, or (ii) patient's prior oral directions if made during hospitalization before two witnesses[5]
2	**Patient, previously when capable, appointed health care agent***	Health care agent decides per PHL 29-C[6]	Health care agent decides per PHL 29-C[7]
3	**Patient has a court-appointed guardian per SCPA Art. 17-A***	Guardian decides per SCPA §1750-b[8]	Guardian decides per SCPA §1750-b[9]
4	**Patient resides in community (and not an OPWDD-licensed residence) and has involved family***	Surrogate decides per FHCDA[10]	Involved family member decides per SCPA §1750-b.[11] The prioritized list of qualified family member is set forth in 14 NYCRR §633.10(a)(7)(iv)(c). Note—A domestic partner or close friend would not qualify.[12]
5	**Patient resides in community (and not an OPWDD-licensed residence) but has no involved family***	Surrogate Decision Making Committee (SDMC) decides per MHL Art. 80[13]	SDMC decides per SCPA §1750-b[14]
6	**Patient resides in OPWDD-licensed or operated facility, is temporarily in a hospital or NH, and has involved family***	Involved family member decides per 14 NYCRR §633.11[15]	Involved family member decides per SCPA §1750-b. The prioritized list of qualified family member is set forth in 14 NYCRR §633.10(a)(7)(iv)(c).[16] Note—A domestic partner or close friend would not qualify.
7	**Patient resides in OPWDD-licensed or operated facility, is temporarily in the hospital or NH, but has no involved family***	SDMC decides per 14 NYCRR §633.11	SDMC decides per SCPA §1750-b.[17]

* Applies only if no row above it applies.

Surrogate Decision Making for Incapable Adult Patients with Mental Illness[18]

A Chart of Applicable Laws and Regulations[19]

	Follow the rules in the first row that applies:	**Decisions in Hospitals (excluding MH unit) and Nursing Homes**	
		A **Consent to Treatment**	**B** **Decision to withdraw or withhold life-sustaining treatment (including entering a DNR Order)**
1	**Patient, previously when capable, left prior written or oral directions**	Follow patient's prior oral or written directions	Follow: (i) patient's prior written directions, or (ii) patient's prior oral directions if made during hospitalization before two witnesses
2	**Patient, previously when capable, appointed health care agent***	Health care agent decides per PHL 29-C	Health care agent decides per PHL 29-C
3	**Patient has court-appointed guardian per MHL Art 81 with health care decision-making authority.***	Guardian with health care decision-making authority decides per the FHCDA[20]	Guardian with health care decision-making authority decides per the FHCDA[21]
4	**Patient resides in community (including an OMH-licensed residence) and has family or close friend***	Surrogate decides per FHCDA[22]	Surrogate decides per FHCDA[23]
5	**Patient resides in community (including and OMH-licensed residence) but has no family or close friend***	(i) Surrogate Decision Making Committee (SDMC) decides per MHL Art. 80 if the patient is eligible [24] (ii) Otherwise, attending physician decides per FHCDA[25]	Attending physician or court decides, per FHCDA[26]
6	**Patient brought to hospital or NH from OMH-licensed or operated psych hospital or unit. Patient has family or close friend.***	(i) If patient was discharged from the OMH-licensed or operated psych hospital or unit, then surrogate decides per FHCDA[27] (ii) If patient was not discharged, then spouse, parent or adult child decides per 14 NYCRR §27.9	(i) For DNR, surrogate decides per PHL Art 29-B (ii) For other decisions, surrogate decides per FHCDA[28]
7	**Patient brought to hospital or NH from OMH-licensed or operated psych hospital or unit. Patient has no family or close friend***	Decision by either (i) SDMC per MHL Art. 80 (ii) Court per §27.9[29]	(i) For DNR, attending phys'n decides per PHL Art. 29-B (ii) For other decisions, attending physician or court decides, per FHCDA[30]

*Applies only if no row above it applies

Endnotes

1. This document is the January 12, 2010 version of a document that appears on the NYS Bar Association Family Health Care Decisions Act Information Center, www.nysba.org/fhcda. It is reprinted here with the permission of the NYS Bar Association.

2. The relevant clauses of the FHCDA are PHL § 2994-b.3-4, which state:

> 3. Prior to seeking or relying upon a health care decision by a surrogate for a patient under this article, if the attending physician has reason to believe that the patient has a history of receiving services for mental retardation or a developmental disability; it reasonably appears to the attending physician that the patient has mental retardation or a developmental disability; or the attending physician has reason to believe that the patient has been transferred from a mental hygiene facility operated or licensed by the office of mental health, then such physician shall make reasonable efforts to determine whether paragraphs (a), (b) or (c) of this subdivision are applicable:
>
> (a) If the patient has a guardian appointed by a court pursuant to article seventeen-A of the surrogate's court procedure act, health care decisions for the patient shall be governed by section seventeen hundred fifty-b of the surrogate's court procedure act and not by this article.
>
> (b) If a patient does not have a guardian appointed by a court pursuant to article seventeen-A of the surrogate's court procedure act but falls within the class of persons described in paragraph (a) of subdivision one of section seventeen hundred fifty-b of such act, decisions to withdraw or withhold life-sustaining treatment for the patient shall be governed by section seventeen hundred fifty-b of the surrogate's court procedure act and not by this article.
>
> (c) If a health care decision for a patient cannot be made under paragraphs (a) or (b) of this subdivision, but consent for the decision may be provided pursuant to the mental hygiene law or regulations of the office of mental health or the office of mental retardation and developmental disabilities, then the decision shall be governed by such statute or regulations and not by this article.
>
> 4. If, after reasonable efforts, it is determined that a health care decision for the patient cannot be made pursuant to subdivision two or three of this section, then the health care decision shall be made pursuant to this article.

3. The chart review group was convened by Lorraine Ryan, Senior Vice President, Legal, Regulatory and Professional Affairs Greater NY Hospital Association and Sara Kaplan-Levenson, Project Manager, Regulatory and Professional Affairs, Greater NY Hospital Association. Participants included John V. Campano (NY Presbyterian), Joan Hauswald (NY Presbyterian), Deborah Korzenik (Continuum Health Partners); Lynn Hallarman, M.D. (SUNY Stony Brook Health Science Center); Jonathan Karmel (NYS Department of Health); Karen Lipson (NYS Department of Health); Carolyn Wolf (Abrams Fensterman). Paul Kietzman (NYSARC) also commented independently. I am very grateful to these reviewers—their work has improved these charts greatly.

4. It would seem that the designation of a surrogate (whether under SCPA §1750-b, 10 NYCRR §633.11 or the FHCDA) is not necessary if the incapable person, previously when capable, personally consented to the treatment.

5. It would seem that the designation of a surrogate (whether under SCPA §1750-b, 10 NYCRR §633.11 or the FHCDA) is not necessary if the incapable person, previously when capable, left clear and convincing evidence of a wish to forgo treatment under the circumstances presented.
The FHCDA, in PHL §2994-d.3(a)(ii), provides guidance as to the type of evidence that would suffice.

6. NY PHL §2982.

7. NY PHL §2982.

8. NY SCPA §1750-b.1.

9. NY SCPA §1750-b.1.

10. NY SCPA §1750-b is inapplicable because its non-court process for authorizing an involved family member, Consumer Advisory Board or SDMC to act as a "guardian" is limited to decisions to withdraw or withhold life-sustaining treatment. See §1750-b.1(a). When a health care decision for the patient cannot be made pursuant to the SCPA or Mental Hygiene Law or regulations, the FHCDA becomes applicable. NY PHL §2994-b.4. Accordingly, the FHCDA becomes applicable, and a FHCDA surrogate can consent to such treatment per PHL §2994-d.

11. NY SCPA §1750-b(a) applies because its non-court process for authorizing a family member to act as guardian applies to decisions to withdraw or withhold life-sustaining treatment. See §1750-b.1(a). Qualified family members are identified in 14 NYCRR §§633.10(a)(7)(iv)(c).

12. The OPWDD surrogate list promulgated pursuant to NY SCPA §1750-b(a) does not provide for the authorizing of a "close friend" to act as "guardian." See 14 NYCRR §633.10(a)(7)(iv)(c). However, NY SCPA §1750-b.1(a) provides that when no other surrogate is available, the MHL Article 80 SDMC may act as guardian for purposes of making the withdrawal or withholding of treatment decision.

13. Most patients with developmental disabilities and who do not a have a guardian or family will qualify for decisions by an SDMC. See MHL §80.3(b).3 (definition of "patient in need of surrogate decision-making"). Moreover, once a person is eligible for decisions by an SDMC, the person remains eligible regardless of a change in residential status. MHL §80.03(b). As a result, the FHCDA provisions on consent for patients without surrogate generally are not applicable. See §2994-b.3(c). In the relatively rare event where SDMC lacks jurisdiction for a patient, the FHCDA would apply.

14. Per NY SCPA §1750-b.1(a), when no other surrogate is available, the MHL Article 80 SDMC may act as guardian for purposes of making the withdrawal or withholding of treatment decision.

15. 14 NYCRR §633.11 provides surrogate decision-making rules for persons who are "residents of a facility operated or certified by OPWDD." Such persons, when hospitalized, are still residents of OPWDD facilities and subject to this regulation.

16. 14 NYCRR §633.10 implements SCPA 1750-b for residents of OPWDD-licensed and operated facilities.

17. See n.11

18. Per PHL §2994-a.21: "Mental illness" means a mental illness as defined in subdivision twenty of section 1.03 of the mental hygiene law, and does not include dementia, such as Alzheimer's disease, or other disorders related to dementia. Per MHL §1.03(2): "Mental illness" means an affliction with a mental disease or mental condition which is manifested by a disorder or disturbance in behavior, feeling, thinking, or judgment to such an extent that the person afflicted requires care, treatment and rehabilitation.
19. This chart points to the applicable law or regulation, but does not provide a complete summary of the applicable law or regulation.
20. PHL §2994-d.1(a).
21. Id.
22. Id.
23. Id.
24. PHL §2994-b.3(c) provides that if a health care decision can be made pursuant to the Mental Hygiene Law, then the decision is governed by such statute. Accordingly, if the decision can be made pursuant to MHL Art. 80 then the decision is governed by MHL Art. 80. Under MHL Art. 80, a decision can be made by an SDMC for a person who is "a resident of a mental hygiene facility including a resident of housing programs funded by an office of the department [of mental hygiene] or whose federal funding application was approved by an office of the department or for whom such facility maintains legal admission status therefor; or receiving home and community-based services for persons with mental disabilities provided pursuant to section 1915 of the federal social security act; or receiving individualized support services .... " Also, note that MHL Art. 80 and the FHCDA have some differences in the scope of major medical treatments that can be authorized pursuant to their procedures.
25. PHL §2994-b.4 provides that " If, after reasonable efforts, it is determined that a health care decision for the patient cannot be made pursuant to subdivision two or three of this section, then the health care decision shall be made pursuant to this article." Accordingly, if MHL Art 80 is inapplicable, then the FHCDA, and specifically PHL §2994-g, becomes applicable.
26. There is no applicable Mental Hygiene Law or OMH regulation. Accordingly, PHL §2994-g.5 applies.
27. If the patient was discharged from the OMH-regulated facility or unit, then OMH regulations become inapplicable, and the FHCDA applies.
28. If the patient was discharged from the OMH-regulated facility or unit, then OMH regulations become inapplicable, and the FHCDA applies. But even if the patient was not discharged, there still is no applicable Mental Hygiene Law or OMH regulation. (MHL Art. 80 is inapplicable because it does not authorize the SDMC to make decisions to withdraw or withhold life-sustaining treatment). Accordingly, per PHL§2994-b.4, the FHCDA becomes applicable.
29. Both provisions are available as a means to secure consent to treatment.
30. There is no applicable mental hygiene law or regulation. (MHL Art. 80 is inapplicable because it does not authorize the SDMC to make decisions to withdraw or withhold life-sustaining treatment). Accordingly, PHL §2994-g.5 applies.

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Albany Medical Center Family Health Care Decisions Act Algorithms

By Danielle E. Holley, J.D., M.S. and Sheila Otto, R.N., B.S.N., M.A.

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Prefatory Notes Concerning the Algorithms

These algorithms are based on the Family Health Care Decision Act (FHCDA) signed into law on March 16, 2010 and codified in New York Public Health Law Art. 29-CC (2010). For example, if a patient has a health care proxy, NY Public Health Law Art. 29-C governs and practictioners should follow the agent's directives.

These algorithms are intended for hospitals and the algorithms for nursing homes would be slightly different.

These algorithms are intended to inform practitioners about the basic steps contemplated by the FHCDA for securing consent on behalf of an incapable patient. They are not intended to foster a mechanical approach to these fact-sensitive and emotionally sensitive cases. Moreover, these algorithms are intended to help guide practitioners but are not intened to cover all possible issues that might arise. Advice regarding disputes or ethical issues, including those concerning proposed health care, should be directed to a member of the Ethics Review Committee. Questions about interpretation of laws, possible court proceedings or other legal issues should be directed to the AMC Legal Department. While seeking advice and counsel as suggested by the directive statements in some of the final boxes of each algorithm, the team should continue to provide care consistent with good medical practice and reasonable medical judgment. In addition, the team should properly document in the medical record as dictated by hospital policy and/or good medical practice; specific documentation is only noted in boxes in chart 3 and 7 to specify circumstances that are unique under the FHCDA.

The FHCDA and these algorithms also do not affect existing law and policy concerning implied consent to health care in an emergency nor do they affect existing law with respect to sterilization.

If a patient regains capacity at any point, the authority of a surrogate or attending physician to make decisions for the patient lapses. The patient with decision-making capacity should give informed consent or refusal for the treatment plan.

There are two situations in which the FHCDA confers binding authority on the Ethics Review Committee decision. These two situations include:

- Chart 5: When an attending physician objects to the surrogate's decision to withhold or withdraw medically administered life-sustaining nutrition and hydration.
- Chart 7: Withholding or withdrawing life-sustaining treatment from an emanicipated minor.

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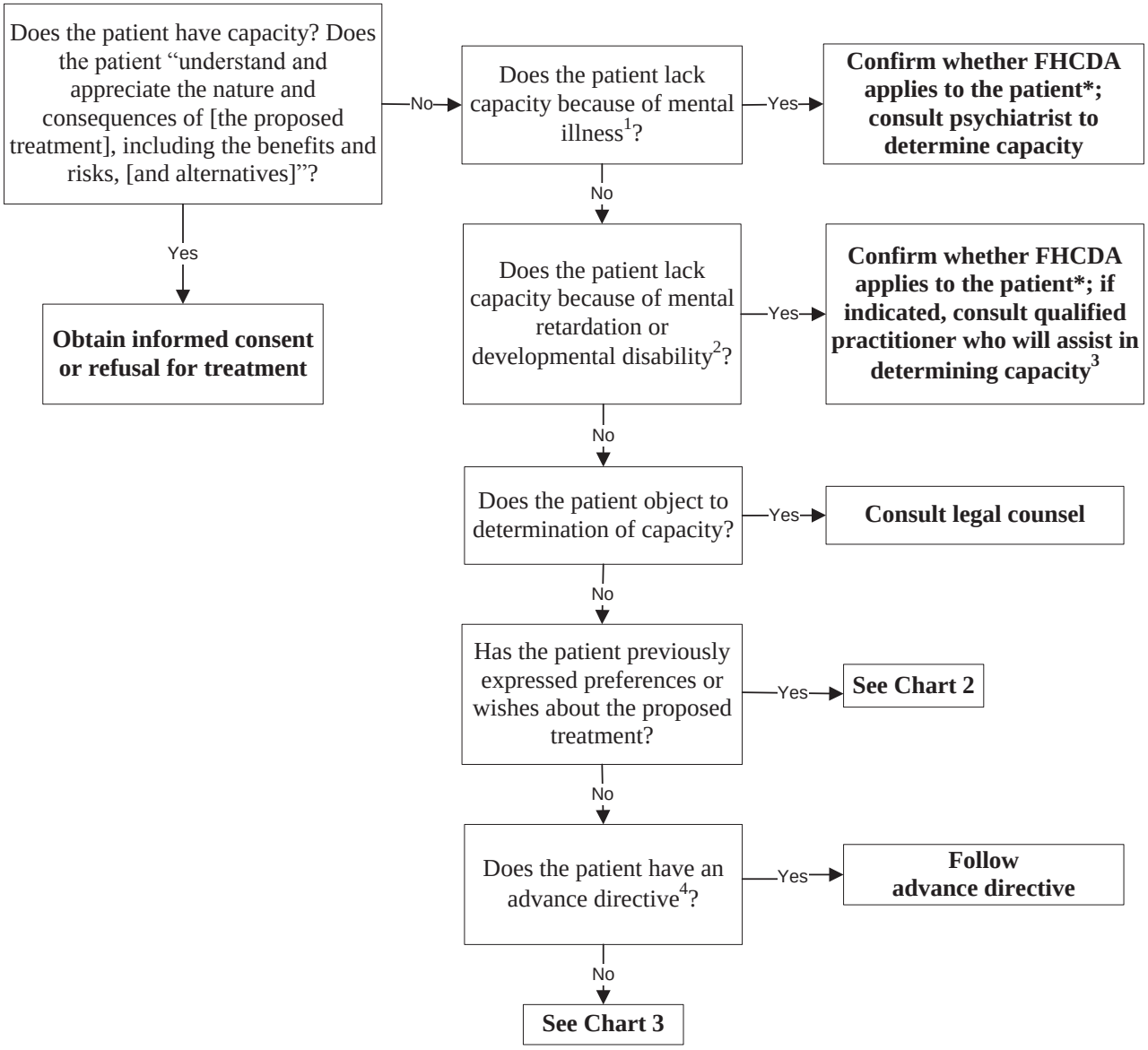
FAMILY HEALTH CARE DECISIONS ACT ALGORITHM

Chart 1: Adult Patient: Determination of Capacity



*** Decisions for most patients who have developmental disabilities, and for some patients who are transferred from mental health facilities, are governed by other laws, in particular the Health Care Decision Act for Persons with Developmental Disabilities. Check applicable policy or consult legal counsel.**

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Chart 2: Adult Patient Without Capacity: Prior Decision

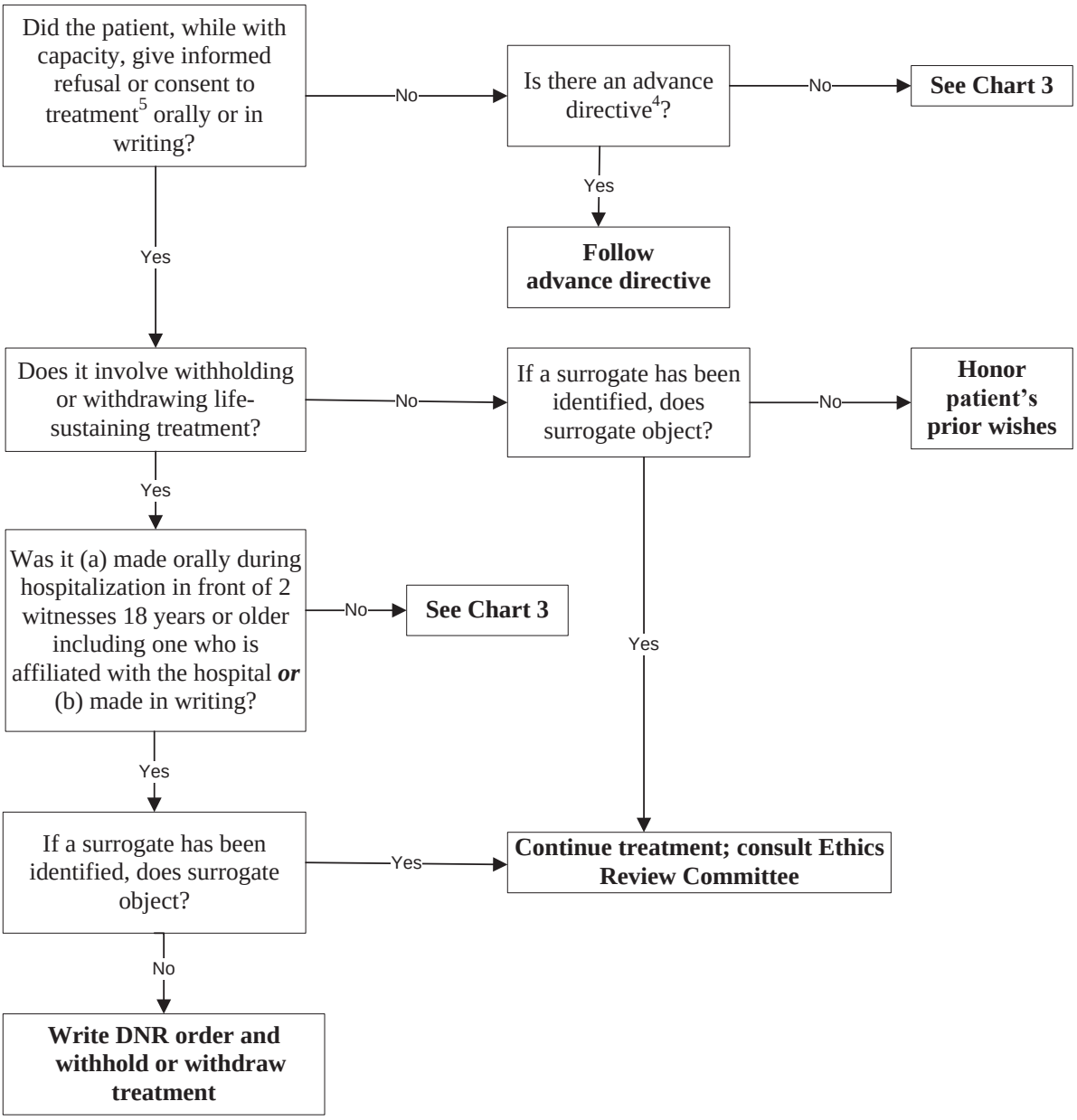

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Chart 3: Adult Patient Without Capacity: Surrogate Designation

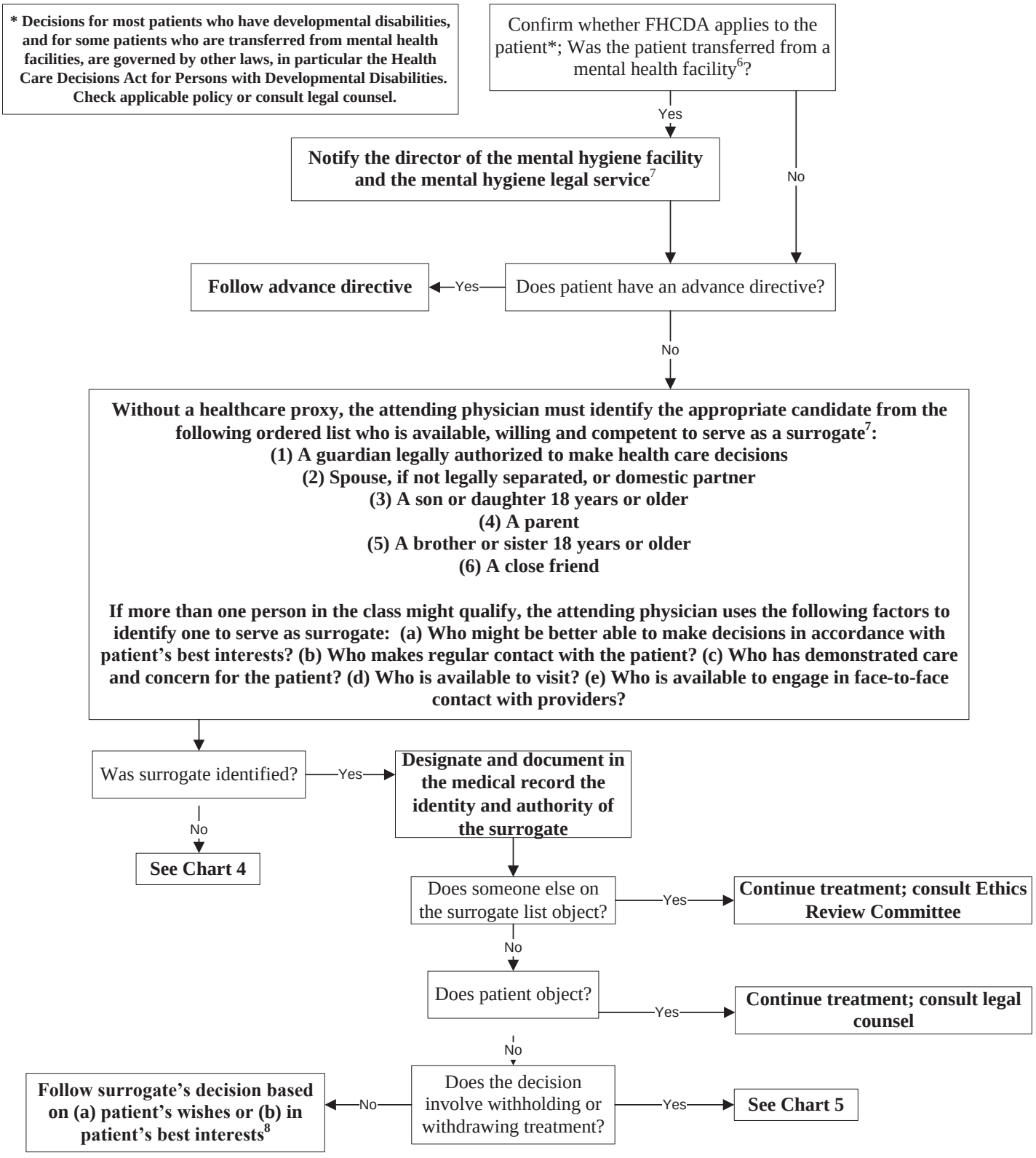

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Chart 4: Adult Patient Without Capacity: No Surrogate

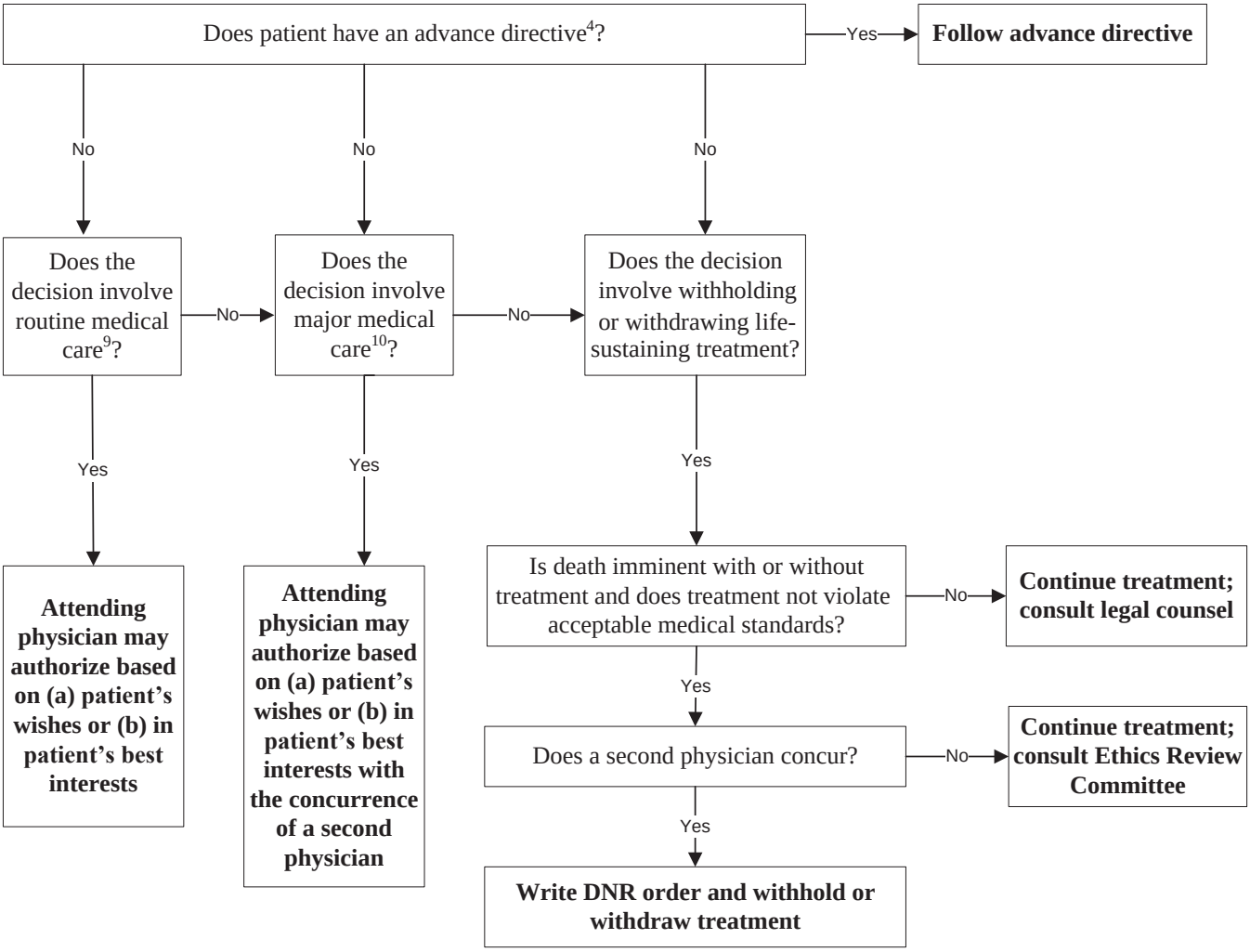

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Chart 5: Adult Patient Without Capacity: Surrogate Identified; Withholding or Withdrawing Life-Sustaining Treatment

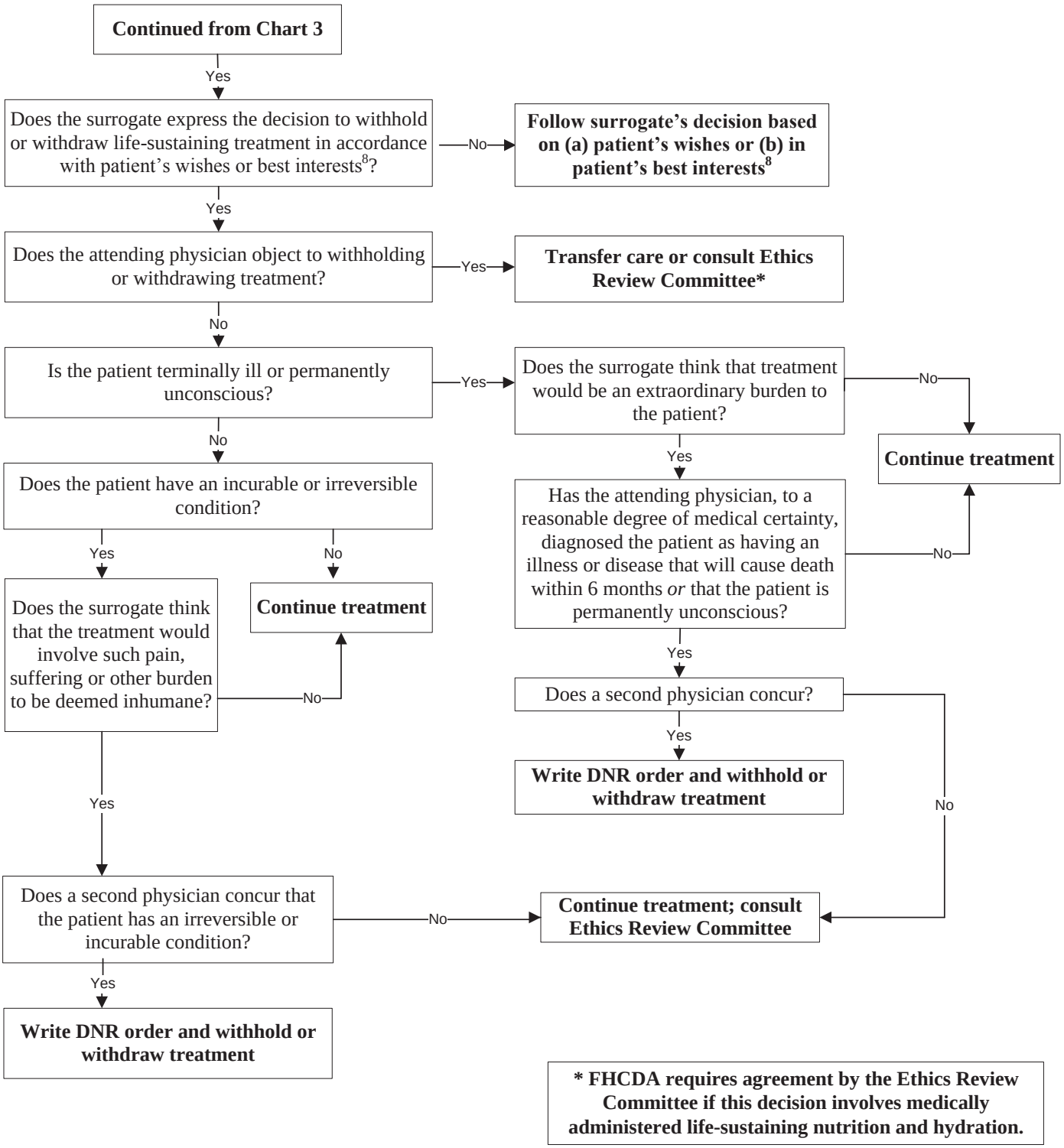

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Chart 6a: Minor Patient: Withholding or Withdrawing Life-Sustaining Treatment

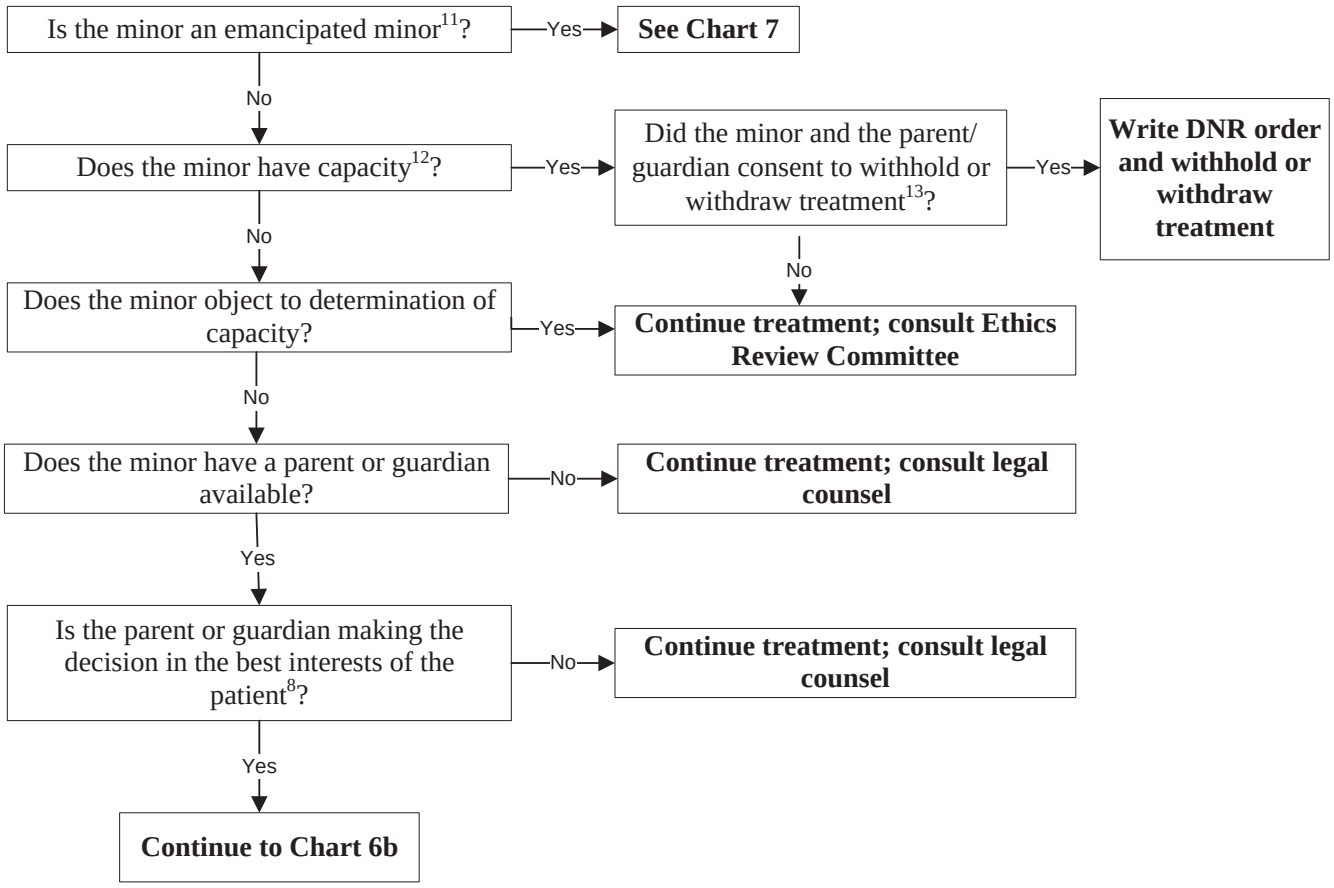

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Chart 6b: Minor Patient: Withholding or Withdrawing Life-Sustaining Treatment

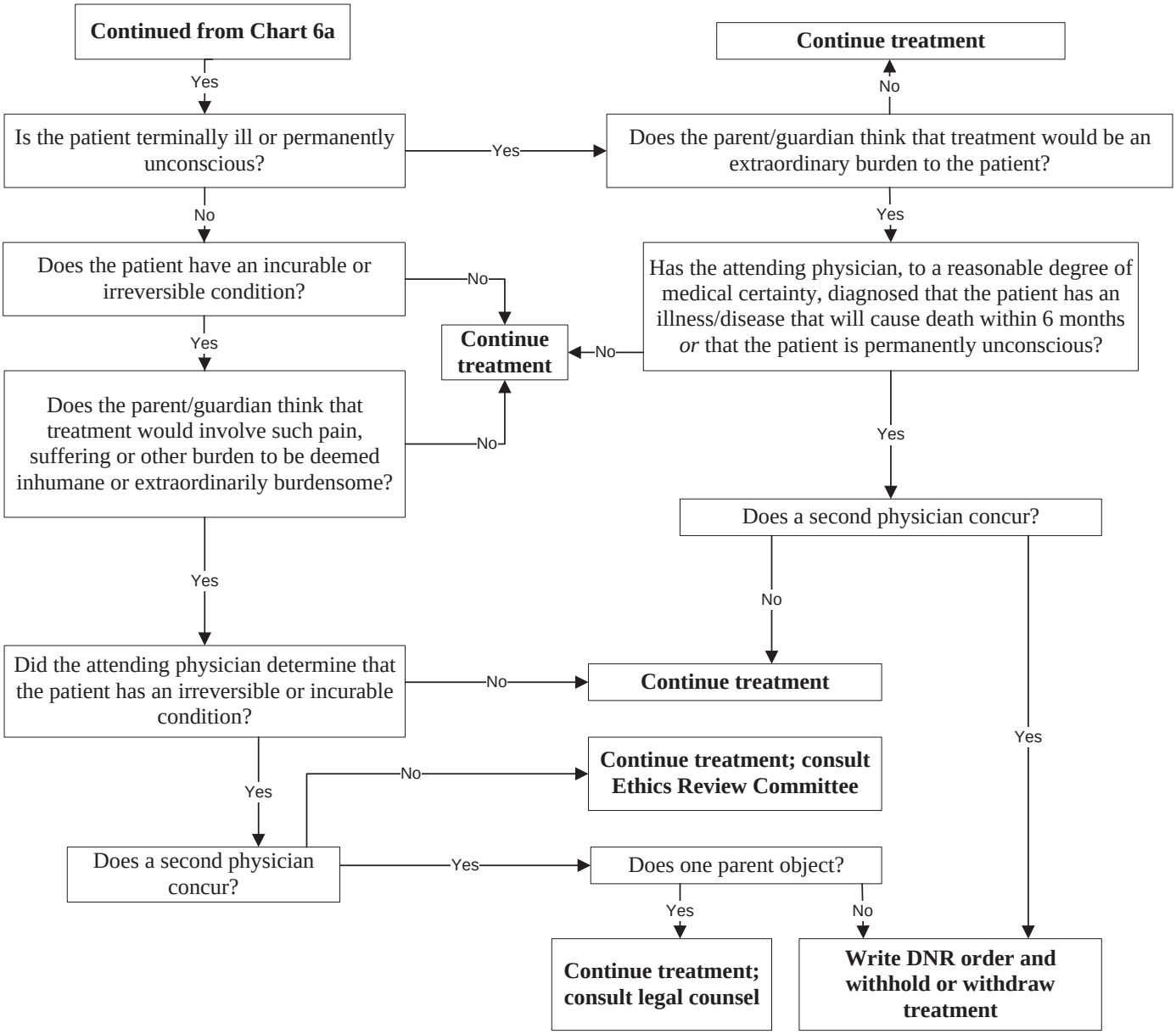

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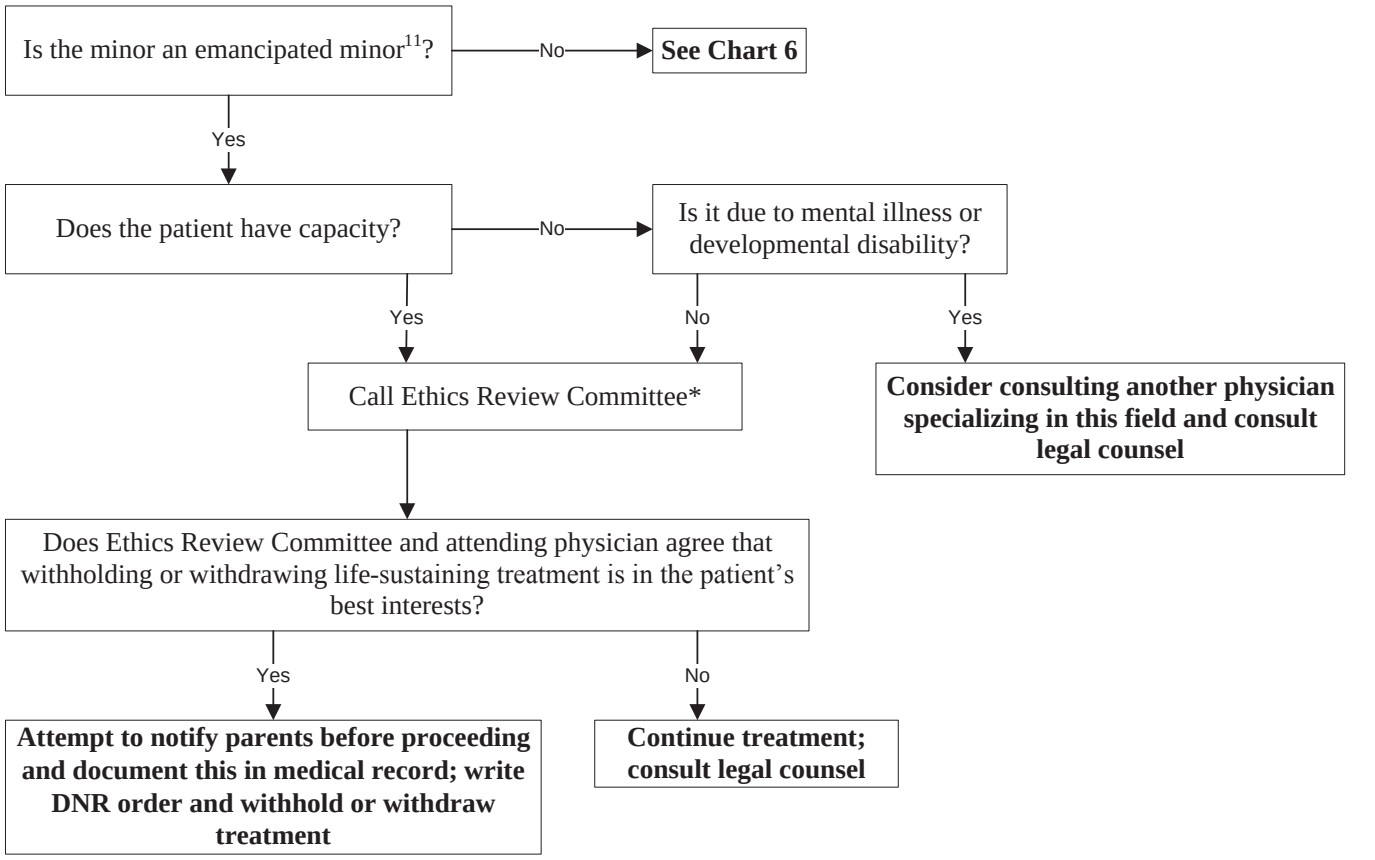
Chart 7: Emancipated Minors: Withholding or Withdrawing Life-Sustaining Treatment



*** FHCDA requires agreement by the Ethics Review Committee if this decision involves medically administered life-sustaining nutrition and hydration.**

Endnotes

1. Mental illness means "a mental disease or condition manifested by a disorder or disturbance in behavior, feeling, thinking, or judgment to such an extent the person afflicted requires care, treatment, and rehabilitation. For purposes of this policy, mental illness does not include dementia or other disorders related to dementia such as Alzheimer's disease."
2. Developmental disability means "a disability that originates before the patient is twenty-two (22) years of age, has continued or can be expected to continue indefinitely, is a substantial handicap to the person's ability to function normally in society, and the condition falls into one of the following categories: (i) is attributable to mental retardation, cerebral palsy, epilepsy, neurological impairment, familial dysautonomia or autism; or (ii) is attributable to any condition closely related to mental retardation that causes a similar impairment of intellectual functioning, or requires treatment and services similar to those with mental retardation; or (iii) is attributable to dyslexia resulting from a disability listed in category (i) or (ii) herein."
3. Either the attending physician must have the following qualifications or another professional with such qualifications must make an independent determination, to a reasonable degree of medical certainty, whether the patient lacks decision-making capacity: a physician or clinical psychologist employed by a developmental disabilities services office named in the Mental Hygiene Law Section 13.17, or has been employed for a minimum of two years to provide care and services in a facility operated by OMRDD, or who has been approved by OMRDD regulations.
4. An advance directive is either (i) a "health care agent" meaning an individual designated by a competent adult using a health care proxy or (ii) a "living will" or medical directive that expresses the patient's wishes or preferences or (iii) a Do-Not-Resuscitate Order that may be expressed on a MOLST Form.
5. Did the patient understand and appreciate the risks and benefits of the proposed treatment including alternatives and either make an informed decision to accept the proposed treatment or refuse the treatment?
6. Mental health facility is a facility operated or licensed by the Office of Mental Health (OMH) or OMRDD, including psychiatric and developmental centers, institutions, clinics, wards, wings or units at hospitals operated to provide services for the mentally disabled.
7. There are restrictions on who may serve as a surrogate including "an operator, administrator, or employee of a hospital or a mental hygiene facility from which the patient was transferred, or a physician who has privileges at the hospital or a health care provider under contract with the hospital may not serve as the surrogate for any adult who is a patient of such hospital, unless such individual is related to the patient by blood, marriage, domestic partnership, or adoption, or is a close friend of the patient whose friendship with the patient preceded the patient's admission to the facility. If a physician serves as surrogate, the physician shall not act as the patient's attending physician after his or her authority as surrogate begins."
8. In assessing the best interests of the patient, the following factors should be taken into consideration: dignity and uniqueness of every person; the possibility and extent of preserving the patient's life; the preservation, improvement or restoration of the patient's health or functioning; the relief of the patient's suffering; and any other values that a reasonable person in the patient's circumstances would wish to consider. Decisions should be patient-centered and consistent with the patient's values, including the patient's religious and moral beliefs, to the extent feasible.
9. Routine medical decisions are "any treatment, service, or procedure to diagnose or treat an individual's physical or mental condition, such as the administration of medication, the extraction of bodily fluids for analysis, or dental care performed with a local anesthetic, for which health care providers ordinarily do not seek specific consent from the patient or authorized representative. It shall not include the long-term provision of treatment such as ventilator support or a nasogastric tube but shall include such treatment when provided as part of post-operative care or in response to an acute illness and recovery is reasonably expected within one month or less."
10. Major Medical Treatment means "any treatment, service or procedure to diagnose or treat an individual's physical or mental condition: (i) where general anesthetic is used; or (ii) which involves any significant risk; or (iii) which involves any significant invasion of bodily integrity requiring an incision, producing substantial pain, discomfort, debilitation or having a significant recovery period; or (iv) which involves the use of physical restraints, as specified in regulations promulgated by the commissioner, except in an emergency; or (v) which involves the use of psychoactive medications, except when provided as part of post-operative care or in response to an acute illness and treatment is reasonably expected to be administered over a period of forty-eight hours or less, or when provided in an emergency."
11. Emancipated Minor is a minor who is the parent of a child, or is 16 years of age or older and living independently from his or her parent(s) or guardian.
12. Minors are presumed to lack the capacity to make decisions about life-sustaining treatment. However, the Attending physician in consultation with the minor's parent(s) or guardian may determine that the minor has capacity make such decisions.
13. An attending physician who has reason to believe that the minor patient has a non-custodial parent or guardian who has not been informed of the decision shall make reasonable efforts to determine if the uninformed parent or guardian has maintained substantial and continuous contact with the minor and, if so, shall make diligent efforts to notify that parent or guardian prior to implementing the decision.

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Comparing the FHCDA to Surrogate Decision Making Laws in Other States

By Thaddeus Mason Pope

I. Introduction

There seem to be at least three distinct missions of this special issue of the *Health Law Journal.* First, several articles have an empirical focus. They describe how the FHCDA has been implemented in hospitals and nursing homes. Second, several articles have a normative focus. They describe how the FHCDA can and should be extended to health care settings (*e.g.* hospice, home care) to which it does not now apply. Third, several articles take a broader normative focus. They explain how the FHCDA might be better implemented (*e.g.* by training ethics committees).

This article serves the third mission. It focuses on those provisions at the heart of the FHCDA: the authorization of surrogates to make health care decisions on the patient's behalf.[1] Specifically, this Article compares the surrogate rules in the FHCDA to the "default" surrogate rules in other states' health care decisions statutes.[2] These comparisons can be usefully grouped into three categories: (1) the surrogate list, (2) the scope of surrogate decision making authority, and (3) the resolution of conflicts between and among surrogates.

II. The Surrogate List

In some respects, the FHCDA is comparatively *broader* than the default surrogate rules in other states. Most notably, the FHCDA includes a "domestic partner" as an equivalent alternative to "spouse" near the top of the priority list. But in other respects, the FHCDA is comparatively *narrower* than the default surrogate rules in other states. For example, the FHCDA includes no provision for the patient's informal, oral designation of a surrogate. It requires strict adherence to the priority order. And the FHCDA surrogate list is shorter than lists in some other states.

A. FHCDA Includes Domestic Partner

In one key respect, the FHCDA is materially broader than the default surrogate rules in many other states. Near the top of the "surrogate list,"[3] "domestic partner" is included as an equivalent alternative to "spouse."[4] The definitions section of the FHCDA defines "domestic partner" as an individual who:

> (a) is formally a party in a domestic partnership or similar relationship with the other person, entered into pursuant to the laws of the United States or of any state, local or foreign jurisdiction,…; or
>
> (b) is formally recognized as a beneficiary or covered person under the other person's employment benefits or health insurance; or
>
> (c) is dependent or mutually interdependent on the other person for support, as evidenced by the totality of the circumstances indicating a mutual intent to be domestic partners….[5]

Significantly, this expansive definition of "domestic partner" includes, among others individuals, a partner in a same-sex couple. New York is one of only fifteen states to have an LGBT-inclusive surrogate selection statute.[6] In contrast, the surrogate lists in a majority of states fail to include domestic partners. While a same-sex partner would probably qualify as a "close friend" in some of these states, that category is usually listed only at the bottom of the surrogate list.[7]

B. FHCDA Omits Patient-Designated Surrogates

New York law provides for three categories of substitute decision makers: (1) court-appointed guardians,[8] (2) patient-appointed agents,[9] and (3) statutorily specified surrogates.[10] The FHCDA omits a fourth type of substitute decision maker that many other states include: patient-designated surrogates.

In several states, the patient not only can formally appoint an agent/proxy but also can informally designate a surrogate.[11] In Tennessee, for example, a patient "may designate any individual to act as surrogate by personally informing the supervising health care provider."[12] This designation may be oral or written. This is an often useful option. For example, if the patient has not completed an advance directive prior to admission, it can be difficult to obtain the necessary witnesses.

Admittedly, if a New York patient expresses a preference about whom she wants as surrogate, that evidence of patient wishes can and should be considered. For example, the designated surrogate might abstain and designate the patient's preferred surrogate.[13] Or the patient's preferred surrogate might object to the decisions of

the designated surrogate.[14] But if the patient's preferred surrogate were not already the highest-ordered potential surrogate under the FHCDA surrogate list, a New York provider could not automatically recognize the patient's preferred surrogate.

C. FHCDA Requires Strict Adherence to the Surrogate List

The FHCDA list of surrogates is a lexical order. Providers may not look to a lower-ordered potential surrogate (*e.g.* sibling) if a higher-ordered potential surrogate (*e.g.* spouse) is available, capable, and willing to serve. While the order is logical and positively correlated to surrogate qualifications, this correlation is hardly assured. Someone lower on the list might be a better decision maker than someone higher on the list.[15] But the higher-ordered individual takes precedence unless she is incapacitated, unavailable, does not want to serve, or designates someone else on the list.

In contrast to the strict priority order under the FHCDA, many other states include a surrogate priority list as only a guideline or suggestion.[16] In Tennessee, for example, the surrogate list is merely something to which "consideration may be given in order of descending preference for service as a surrogate."[17] The best qualified surrogate might be at the bottom of the surrogate list. In identifying the patient's surrogate, the supervising health care provider is primarily looking for an "adult who has exhibited special care and concern for the patient, who is familiar with the patient's personal values, who is reasonably available, and who is willing to serve."[18]

The Tennessee statute provides five mandatory criteria for determining the person best qualified to serve as the surrogate: (1) whether the proposed surrogate reasonably appears to be better able to make decisions either in accordance with the known wishes of the patient or in accordance with the patient's best interests; (2) the proposed surrogate's regular contact with the patient prior to and during the incapacitating illness; (3) the proposed surrogate's demonstrated care and concern; (4) the proposed surrogate's availability to visit the patient during the patient's illness; and (5) the proposed surrogate's availability to engage in face-to-face contact with health care providers for the purpose of fully participating in the decision making process.[19]

In contrast, the FHCDA includes a consideration of surrogate qualifications only in determining whether an individual qualifies as a "close friend."[20] Individuals in other classes of surrogates are qualified by their relationship status alone. Admittedly, if the FHCDA were too demanding in terms of surrogate qualifications, that could undermine a key objective of the statute: to erase the clear and convincing evidence hurdle.[21] But there is clearly enough middle ground to afford greater flexibility in surrogate designation.

D. FHCDA Has a Comparatively Shorter Surrogate List

The FHCDA has a priority list that is composed primarily of family members. After all, these are the individuals most likely to know and care about the patient. If none of these is available, then providers may designate a "close friend."[22] But the listed family members on the surrogate list are limited to: (1) spouse or domestic partner, (2) adult children, (3) parents, and (4) adult siblings.[23]

In contrast, the priority lists in other states' surrogate decision making laws also include other, more distant family members.[24] Many states include: adult grandchildren,[25] adult nieces and nephews,[26] adult uncles and aunts,[27] grandparents,[28] and cousins.[29] In many cases, the omission of such individuals from the FHCDA surrogate list is probably of little consequence. If higher-ordered individuals on the list were unavailable, then these more distant family members might qualify as a "close friend." However, there are surely many such relatives who will not qualify, because they do not maintain the "regular contact" with the patient necessary to be familiar with the patient's activities, health, and religious or moral beliefs.

III. Scope of Surrogate Decision Making Authority

Just as the FHCDA is comparatively broader than the laws in other states with respect to the surrogate list, it is also comparatively broader with respect to the scope of the surrogate's decision making authority. Most notably, the FHCDA permits a surrogate to stop life-sustaining treatment in a broader range of circumstances (and not just when the patient is terminally ill or permanently unconscious). The FHCDA does not restrict decisions concerning either pregnant women or artificial nutrition and hydration. But in other respects, the FHCDA is comparatively narrower than the default surrogate rules in other states. The FHCDA applies only to hospitals and nursing homes. And it does not apply to oral nutrition and hydration.

A. FHCDA Allows a Surrogate to Stop Inhumane or Extraordinarily Burdensome Treatment

Many states permit a surrogate to withhold or withdraw life-sustaining medical treatment only when the patient is either terminally ill or permanently unconscious.[30] Moreover, "terminal illness" is typically defined narrowly to include a "disease, illness or condition… for which there is no reasonable medical expectation of recovery and which, as a medical probability, will result in the death of such human being regardless of the use or discontinuance of medical treatment."[31]

The FHCDA similarly permits a surrogate to withdraw life-sustaining treatment when (1) "the patient has an illness or injury which can be expected to cause death within six months, whether or not treatment is provided," or (2) when "the patient is permanently unconscious."[32] Indeed, even when one of these conditions is satisfied, the FHCDA additionally requires the surrogate to establish that the treatment would be "an extraordinary burden to the patient."[33]

But, unlike many other states, the FHCDA also permits a surrogate to withdraw life-sustaining treatment when none of the above conditions are satisfied. The FHCDA alternatively permits a surrogate to establish: (1) that the provision of treatment would involve "such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances," and (2) that the patient has an "irreversible or incurable condition."[34] The FHCDA thereby materially expands the conditions under which a surrogate can stop life-sustaining medical treatment. Many chronic conditions are "irreversible" and/or "incurable," even though they might not qualify as a "terminal illness" in other states. And the determination of inhumanness and burdensomeness is left to the discretion and judgment of the surrogate.

B. FHCDA Includes No Pregnancy Limitation

Many states do not allow a surrogate to withhold or withdraw life-sustaining treatment from a patient known to be pregnant, if continued treatment would permit the fetus to be viable outside the uterus.[35] The FHCDA has no such limitation, thus assuring the primacy of the patient's autonomy.

C. FHCDA Includes No ANH Limitation

Health care decisions statutes often treat artificial nutrition and hydration differently from other forms of life-sustaining medical treatment. Many states impose special additional conditions on surrogate decisions to withhold or withdraw artificial nutrition and hydration.[36] The FHCDA includes no such prohibition or limitation.[37]

D. FHCDA Only Applies to Hospitals and Nursing Homes

The application of the FHCDA is limited to hospitals and nursing homes.[38] This restriction is unique. The surrogate decision making rules in every other state apply to any type of provider that is licensed, certified or otherwise authorized or permitted by law to provide health care.[39]

Fortunately, the New York legislature was aware of this uncommon limitation and the potential need to expand the scope of the FHCDA's application. The legislature directed the New York Task Force on Life and the Law to "consider whether the FHCDA should be amended to apply to health care decisions in [other] settings."[40] While the Task Force is still deliberating over extensions of the FHCDA, it has already made an initial recommendation that the FHCDA be amended to include surrogate decision making in the context of hospice care.[41] The FHCDA already includes extra safeguards for surrogate decision making in nursing homes (as compared to general hospitals). Amendments to the FHCDA could include similar safeguards for the FHCDA's application to other treatment contexts.[42]

E. FHCDA Does Not Apply to Oral Nutrition and Hydration

The preface to the FHCDA states that "the legislature does not intend to encourage or discourage any particular health care decision or treatment."[43] Nevertheless, the legislature explicitly observed that it "does not intend to authorize a surrogate to deny to the patient food [and] water."[44] A New York patient with capacity may refuse food and water by mouth.[45] But the FHCDA does not permit a surrogate to deny a patient "nutrition or hydration orally, without reliance on medical treatment."[46] New York is one of only about five states to explicitly exclude oral food and fluids from the scope of surrogate decision making authority.[47]

Voluntarily stopping eating and drinking, also referred to as voluntary refusal of food and fluid, is a peaceful and comfortable method to allow death. It is accepted by the best palliative care physicians in New York.[48] Just as decisions regarding other treatment typically cannot be made by the patient at the relevant time, patients will similarly lack capacity to make a decision to stop food and fluid at the time they would want. Take, for example, the patient with severe dementia who can no longer recognize her children or go to the bathroom. This patient's surrogate could not stop oral food and fluids even if she knew that the patient never wanted to live like that.[49]

F. FHCDA Limits the Authority of the Residual Surrogate

For patients without surrogates, the FHCDA permits providers to withhold or withdraw life-sustaining treatment only (1) with a court order, or (2) if an attending with the concurrence of a second physician determines that the treatment would be medically ineffective or contrary to the standard of care.[50] In effect, this second alternative makes the attending physician a surrogate. But the scope of this surrogate's discretion is significantly limited.

In contrast, other states permit physicians to stop life-sustaining treatment in a broader range of circum-

stances, often with the concurrence of the ethics committee.Interestingly, almost none of these states set minimum standards for ethics committees. In contrast, the FHCDA sets comprehensive standards. Accordingly, if the ethics committees in any state should have authority to resolve these disputes, it should be a New York ethics committee.[51]

IV. FHCDA Lacks an Authoritative Mechanism for the Resolution of Surrogate Conflicts

The FHCDA gives the newly mandated "ethics review committees" several "advisory and nonbinding" roles and several authoritative roles. But with respect to surrogate conflicts, the FHCDA gives the ethics committees a merely advisory role.[52] When any person on the surrogate list objects to the designation of the surrogate[53] or objects to a surrogate's decision,[54] the attending physician must "promptly refer the matter to the ethics review committee." But while referral is mandatory, the outcome of the ethics committee review is merely advisory.[55]

In contrast, other states give the ethics committee adjudicatory authority to resolve these disputes. For example, Delaware provides that "if persons with equal decision making priority…cannot agree who shall be a surrogate or disagree about a health-care decision," then the attending physician or anyone on the surrogate list may refer the case to the ethics committee.[56] Significantly, the statute further provides: "A physician who acts in accordance with the recommendation of the committee is not subject to civil or criminal liability or to discipline for unprofessional conduct for any claim based on lack of consent or authorization for the action."[57] Because New York ethics committees are comparatively more robust, they could serve this dispute resolution role.

V. Conclusion

The FHCDA is a tremendous positive achievement for New York. It will surely help assure that incapacitated individuals receive the medical treatment that they would have chosen for themselves. Still, just as other states continue to amend their health care decisions statutes in response to developing data, New York should be prepared to do the same.

Endnotes

1. *See* N.Y. Pub. Health Law § 2994-d.
2. By "default" surrogate, I refer to a substitute decision maker identified by reference to the state's Health Care Decisions Act, when neither the patient has named an agent/proxy/DPAHC nor the court a guardian/conservator. For the sake of manageability, this article focuses on surrogates making treatment decisions other than for DNR on behalf of adult patients who are not mentally disabled.
3. N.Y. Pub. Health Law § 2994-a(30).
4. N.Y. Pub. Health Law § 2994-d(1)(B).
5. N.Y. Pub. Health Law § 2994-a(7). The definition further provides that intent to be domestic partners can be evidenced by, among other things, "common ownership or joint leasing of real or personal property; common householding, shared income or shared expenses; children in common; signs of intent to marry…."
6. *See* Matthew Stiff, *Breaking Down Barriers: An Administrator's Guide to State Law and Best Policy Practice for LGBT Healthcare Access,* at 13 (Human Rights Campaign May 2009); Lesley S. Castillo et al., *Lost in Translation: The Unintended Consequences of Advance Directive Law on Clinical Care,* 154 Annals Internal Med. 121, 123 (2011).
7. *See, e.g.,* Alaska Stat. § 47.24.016(a)(6); Ark. Rev. Stat. § 36-3231(A)(6); Del. Code Ann., tit. 16 § 2507(b)(3); Fla. Stat. Ann. § 765.401(1)(g); W. Va. Code § 16-30-8(a)(6).
8. N.Y. Pub. Health Law § 2994-a(15); N.Y. Pub. Health Art. 29-B.
9. N.Y. Pub. Health Law § 2994-a(13); N.Y. Pub. Health Art. 29-C.
10. N.Y. Pub. Health Law §§ 2994-a(29) & 2994-d.
11. *See, e.g.,* Alaska Stat. § 13.52.030(c); Cal. Prob. Code § 4711(a); Del. Code Ann., tit. 16 § 2507(b)(1); Haw. Rev. Stat. § 327E-5(a); Miss. Code Ann. § 41-41-211(2); N.M. Stat. Ann. § 24-7A-5(B); Wyo. Stat. § 35-22-406(b).
12. Tenn. Code Ann. § 68-11-1806(a).
13. N.Y. Pub. Health Law § 2994-d(1).
14. N.Y. Pub. Health Law § 2994-f(2)(B).
15. One exception to the strict order is that the identified surrogate "may designate any other person on the list to be surrogate, provided no one in a class higher in priority than the person designated objects." N.Y. Pub. Health Law § 2994-d(1).
16. Colo. Rev. Stat. § 15-18.5-103(4); Haw. Rev. Stat. § 327E-5(d); N.D. Cent. Code § 23-12-13(1); Tenn. Code Ann. § 68-11-1806(b)(3)-(4); W. Va. Code § 16-30-8(b).
17. Tenn. Code Ann. § 68-11-1806(c)(3).
18. Tenn. Code Ann. § 68-11-1806(c)(2).
19. Tenn. Code Ann. § 68-11-1806(c)(4).
20. N.Y. Pub. Health Law § 2994-d(1)(F).
21. *See* Jack Freer & Stephen Wear, *Culture Wars in New York State: Ongoing Political Resistance by Religious Groups to the Family Health Care Decisions Act,* 8 Christian Bioethics 9 (2002); Bernadette Tuthill, *Want to Terminate Life Support? Not in New York: Time to Give New Yorkers a Choice,* 26 Touro L. Rev. 675 (2010).
22. N.Y. Pub. Health Law § 2994-d(1)(F). The FHCDA defines "close friend" as an adult who "has maintained such regular contact with the patient as to be familiar with the patient's activities, health, and religious or moral beliefs, and who presents a signed statement to that effect to the attending physician." N.Y. Pub. Health Law § 2994-a(4).
23. N.Y. Pub. Health Law § 2994-d(1)(B)-(E).
24. *See, e.g.,* Tenn. Code Ann. § 68-11-1806(c)(3)(E) ("any other adult relative of the patient"); Va. Code § 54.1-2986(A)(6) ("any other relative").
25. *See, e.g.,* Del. Code. Ann., tit. 16 § 2507(b)(2)(e); Ga. Code Ann. § 31-9-2(a)(6)(E); 755 Ill. Comp. Stat. 40/25(a)(6); Me. Rev. Stat., tit. 18A § 5-805(b)(5); Pa. Stat. Ann., tit. 20 § 5461(d)(1)(v); S.C. Code Ann. § 44-66-30(A)(6); S.D. Codified Laws § 34-12C-3(5); Utah Code Ann. § 75-2a-108(1)(b)(ii)(D);Wis. Stat. Ann. § 50.06(3)(f); Wyo. Stat. § 35-22-406(b)(vi).

26. *See, e.g.,* Del. Code. Ann., tit. 16 § 2507(b)(2)(f); Ga. Code Ann. § 31-9-2(a)(6)(F); Me. Rev. Stat., tit. 18A § 5-805(b)(6); S.D. Codified Laws § 34-12C-3(6).
27. *See, e.g.,* Ga. Code Ann. § 31-9-2(a)(6)(F); Me. Rev. Stat., tit. 18A § 5-805(b)(7); S.D. Codified Laws § 34-12C-3(6).
28. *See, e.g.,* Ga. Code Ann. § 31-9-2(a)(6)(D); N.M. Stat. Ann. § 24-7A-5(B)(6); S.C. Code Ann. § 44-66-30(A)(6); S.D. Codified Laws § 34-12C-3(5); Utah Code Ann. § 75-2a-108(1)(b)(ii)(F); Wis. Stat. Ann. § 50.06(3)(e); Wyo. Stat. § 35-22-406(b)(iv).
29. *See, e.g.,* S.D. Codified Laws § 34-12C-3(6).
30. *See, e.g.,* Ala. Code § 22-8A-11(a)(2); Del. Code. tit. 16 § 2507(b)(6) ("A surrogate may make a decision to provide, withhold or withdraw a life-sustaining procedure if the patient has a qualifying condition…."); Iowa Code Ann. § 144A.7(1); Me. Rev. Stat. tit. 18-A § 5-805(a); Mont. Code Ann. § 50-9-106(1)(a); Nev. Rev. Stat. § 449.626(1)(a); N.C. Gen. Stat. § 90-322(a)(1a); Ohio Rev. Code § 2133.08(D)(2). *See also* Muriel R. Gillick, *The Use of Advance Care Planning to Guide Decisions about Artificial Nutrition and Hydration,* 21 Nutrition in Clinical Practice 126 (2006).
31. Del. Code, tit. 16 § 2501(r).
32. The standards are more demanding when the patient is in a residential health care facility. N.Y. Pub. Health Law § 2994-d(5)(b).
33. N.Y. Pub. Health Law § 2994-d(5)(a)(i).
34. N.Y. Pub. Health Law § 2994-d(5)(a)(ii).
35. *See, e.g.,* Alaska Stat. § 13.52.055(b); Ga. Code Ann. § 31-32-9(a); Iowa Code Ann. § 144A.7(3); Ky. Rev. Stat § 311.639(4); Mont. Code Ann. § 50-9-106(7); Nev. Rev. Stat. § 449.626(6).
36. *See, e.g.,* Haw. Rev. Stat. § 327E-5(g); Ky. Rev. Stat § 311.629(3); Okla Stat. Ann., tit. 63 §§ 3080.3-.4; Tenn. Code Ann. 68-11-1806(e). *See generally* Carol E. Seiger et al., *Refusing Artificial and Hydration: Does Statutory Law Send the Wrong Message?* 50 J. Am. Geriatrics Soc'y 544 (2002).
37. The FHCDA does specify a special procedure where a provider objects to a surrogate's decision to "withdraw or withhold nutrition and hydration provided by means of medical treatment." N.Y. Pub. Health Law § 2994-d(5)(c).
38. N.Y. Pub. Health Law § 2994-b(1) ("This article shall apply to health care decisions regarding health care provided in a hospital to a patient…."); N.Y. Pub. Health Law § 2994-a(18) (defining "hospital" as a "general hospital or a residential health care facility"); N.Y. Pub. Health Law § 2994-a(25) (defining "patient" as a "person admitted to a hospital").
39. *See, e.g.,* Cal. Prob. Code §§ 4619 & 4621; Del. Code,. tit. 16 § 2501(i)-(j).
40. 2010 N.Y. Laws Ch. 8, § 28 (2).
41. New York State Task Force on Life and the Law, *Recommendations Regarding the Extension of the Family Health Care Decisions Act to Include Hospice* (Nov. 30, 2010).
42. For example, multi-institutional ethics committees could be established for smaller facilities that cannot staff and support their own committees. *See* Thaddeus Mason Pope, *Multi-Institutional Healthcare Ethics Committees: the Procedurally Fair Internal Dispute Resolution Mechanism*, 31 Campbell L. Rev. 257 (2009).
43. N.Y. Pub. Health Law Art. 29-CC § 1.
44. *Id.*
45. *See, e.g., A.B. v. C*, 477 N.Y.S. 2d 281 (N.Y. Sup. Ct. 1984); *In re Plaza Health & Rehabilitation Center,* Sup. Ct., Unandaga Cty., Syracuse, N.Y. (Feb. 2, 1984).
46. N.Y. Pub. Health Law § 2994-d(4)(d) ("Providing nutrition and hydration orally, without reliance on medical treatment, is not health care under this article and is not subject to this article."); *id.* § 2994-a(12).
47. *See* Thaddeus M. Pope & Lindsey E. Anderson, *Voluntarily Stopping Eating and Drinking: A Legal Treatment Option at the End of Life,* 17 Widener L. Rev. No. 2 (forthcoming 2011).
48. *See, e.g.,* Franklin G. Miller & Diane E. Meier, *Voluntary Death: A Comparison of Terminal Dehydration and Physician-Assisted Suicide*, 128 Annals Internal Med. 559, 559 (1998); Timothy E. Quill & Ira R. Byock, *Responding to Intractable Terminal Suffering: The Role of Terminal Sedation and Voluntary Refusal of Food and Fluids,* 132 Annals Internal Med. 408, 412 (2000); Timothy Quill, et al., *Palliative Options of Last Resort: A Comparison of Voluntarily Stopping Eating and Drinking, Terminal Sedation, Physician Assisted Suicide, and Voluntary Active Euthanasia, in* GIVING DEATH A HELPING HAND 49 (D. Birnbacher & E. Dahl eds., 2008).
49. *See* Stanley A. Terman, *Peaceful Transitions: An Ironclad Strategy to Die When and How YOU Want* (2009); Stanley A. Terman, *The Best Way to Say Goodbye: A Legal Peaceful Choice At the End of Life* (2007).
50. N.Y. Pub. Health Law § 2994-g(5).
51. *See* Thaddeus Mason Pope, *Legal Briefing: Healthcare Ethics Committees,* 22 J. Clinical Ethics (forthcoming 2011).
52. Unfortunately, such conflicts are common. *Cf.* Elise G. McIntosh, *Adult Children Often Don't See Eye-to-Eye When Tending to their Parents' Needs,* Staten Island Advance, Jan. 18, 2011.
53. N.Y. Pub. Health Law § 2994-f(2)(b).
54. N.Y. Pub. Health Law § 2994-f(2)(c).
55. N.Y. Pub. Health Law § 2994-m(2)(c).
56. Del. Code, tit. 16 § 2507(b)(8).
57. *Id.* In nearly half the states conflicts among surrogates of the same class are determined by majority vote.

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The Palliative Care Information Act and Its Applicability to Cases Subject to the Family Health Care Decisions Act

By David C. Leven

Introduction

The Palliative Care Information Act,[1] which became effective on February 9, 2011, requires the attending health care practitioner of a patient who is terminally ill to offer information about palliative care and end-of-life treatment options. The Palliative Care Information Act and the Family Health Care Decisions Act will often apply simultaneously to the same clinical cases. Therefore, it is important for health care attorneys and health care practitioners not only to be familiar with both of these laws, but to understand the connection between them. Health care attorneys should play a prominent role in ensuring that their clients are aware of and comply with the Palliative Care Information Act and with the Family Health Care Decisions Act when these laws intersect.

Pursuant to the Family Health Care Decision Act (FHCDA), a surrogate has the right to receive medical information and medical records necessary to make informed decisions about health care for the patient. Specifically, health care providers must provide information including the diagnosis, prognosis and the risks and benefits of alternative treatment options.[2]

When a determination is made that the patient has a terminal illness or condition and death can be reasonably expected within six months, whether or not treatment is provided, the Palliative Care Information Act (PCIA) becomes operative. It is applicable to surrogates when a patient with a terminal illness or condition who does not have a health care agent lacks capacity to reasonably understand and make informed choices related to palliative care.[3] After a determination has been made that the patient lacks decision making capacity, in accordance with the FHCDA, the surrogate is entitled, under the PCIA, to receive important relevant information and counseling that would otherwise have been offered to a patient with capacity.

Summary of the Palliative Care Information Act

The key provision of the law states:

> If a patient is diagnosed with a terminal illness or condition, the patient's attending health care practitioner shall **offer (emphasis added)**[4] to provide the patient with information and counseling regarding palliative care and end-of-life options appropriate to the patient, including but not limited to: the range of options appropriate to the patient; the prognosis, risks and benefits of the various options; and the patient's legal rights to comprehensive pain and symptom management at the end of life.[5]

Additionally,

a. The obligation to provide such information and counseling can be fulfilled by the attending physician or nurse practitioner or by referral or transfer to another appropriate health care practitioner.[6]

b. Information can be provided verbally, or in writing.[7]

c. A surrogate may decline the offer to receive the information and/or counseling.[8]

Comment: If an offer to provide information and counseling is declined, the practitioner should renew the offer, as appropriate, when the patient's condition changes and different treatment options may be available (see section on counseling on p. 116).

Definitions:

- "**Appropriate**" means consistent with applicable legal, health and professional standards; the patient's clinical and other circumstances; and the patient's reasonably known wishes and beliefs.
- "**Attending health care practitioner**" means a physician or nurse practitioner who has primary responsibility for the care and treatment of the patient. Where more than one physician or nurse practitioner share that responsibility, each of them has responsibility under this section, unless they agree to assign that responsibility to one of them.
- "**Palliative care**" means health care treatment, including interdisciplinary end-of-life care, and consultation with patients and family members, to prevent or relieve pain and suffering and to enhance the patient's quality of life, including hospice care under article forty of [the Public Health Law].

- "**Terminal illness or condition**" means an illness or condition which can reasonably be expected to cause death within six months, whether or not treatment is provided.[9]

The Need for the Palliative Care Information Act

The PCIA, a model for the nation, was needed for many critically important reasons despite the well established right of patients to have information sufficient to make informed decision about their treatment.

First, at the end of life, physicians have often been unwilling to have discussions with their patients about their diagnosis, prognosis and treatment options or those discussions have been inadequate. One study involving 332 advanced cancer patients who were followed from the time they were enrolled until they died (an average of 4.4 months) found that only 123 of those patients had end-of-life discussions with their physicians.[10]

The lack of physician-patient communication is one reason why hospice referrals have been made so near death or not at all. In New York State 33% of patients were enrolled for only 7 days or less and 32% were enrolled for 31 days or less in 2008, the last year for which figures are available, http://www.nyhealth.gov/statistics/facilities/hospice/utilization_and_cost/2008/11. Since patients are eligible for hospice when it is likely that they will die within six months and hospices generally provide excellent end-of-life care and have been extremely beneficial for the vast majority of patients and their families, referrals should be made much earlier for most patients. Compliance with the PCIA will result in more and earlier referrals to hospice.

Secondly, the vast majority of dying patients in fact want to know their diagnosis and prognosis. In one study of 214 persons aged 60 and older with a limited life expectancy secondary to cancer, congestive heart failure, or chronic obstructive pulmonary disease, 83% of those believing they had 1 year or less to live wanted to discuss prognosis.[12]

And, in a recent survey 95% of patients with 3 different forms of cancer wanted their oncologist to be honest about their expected survival.[13]

Thirdly and most importantly, when discussions take place between physicians and their dying patients, quality of life is improved, decisions are made for less aggressive interventions, lives are extended, patient's wishes are more likely to be respected, and hospice referrals occur sooner.[14] One recent study found that patients with terminal lung cancer who began receiving palliative care immediately upon diagnosis as compared to patinets receiving standard care not only were happier, more mobile and in less pain as the end neared—but they also lived nearly three months longer.[15]

In addition, patients with cancer are more likely to receive end-of-life (EOL) care that is consistent with their preferences when they have had the opportunity to discuss their wishes for EOL care with a physician.[16]

Finally, cost savings result when end-of-life discussions take place. According to a 2009 study, patients with advanced cancer who reported having EOL conversations with physicians (only 31% of the patients had such discussions) had significantly lower health care costs in their final week of life. Higher costs were associated with worse quality of death. Additionally the study found that patients who had EOL discussions with their physicians "were more likely to receive outpatient hospice care and be referred to hospice earlier."[17]

Implementation of the Palliative Care Information Act

It is important that the PCIA be effectively implemented. Affected patients are dying and this will be a very difficult time for them and surrogates who are empowered to make decisions for them. Health care attorneys should be helpful in working with their health care professional colleagues, as well as their clients, to ensure successful implementation.

The new law only requires the provision of information and counseling concerning palliative care to patients with an illness or condition that is reasonably expected to cause death within six months. However, this of course does not bar the provision of information and counseling to surrogates where the patients are outside the terminal diagnosis—i.e., patients who are seriously or chronically ill. In fact it is often clinically appropriate to do so earlier. Health care attorneys can help facilitate compliance with the strict requirements of the law and recommend that earlier conversations take place with their institutional clients. Attorneys who have individual clients who are seriously or terminally ill can act similarly.

Informing Health Care Professionals About the Palliative Care Information Act

Health care professionals need to know about the content of the FHCDA to ensure compliance and they need to understand its connection, when applicable, to the Family Health Care Decisions Act. Physicians, nurse practitioners, nurses, and social workers all perform key roles in helping patients at the end of life so they will need to know what is required by the law and where they can assist patients and surrogates to effectively implement it. The New York State Department of Health has reached out to physicians and nurse practitioners but it

will not be able to reach all who are affected by the law. Additionally, students in medical, nursing and social work schools need to be educated about the PCIA, preferably during courses, which should be required, on palliative and end-of-life care. Health care attorneys who have affiliations with hospitals, nursing homes, health care professional schools, etc., are urged to assist to ensure that the PCIA has been brought to the attention of health care professionals and that they have or will receive appropriate training.

NYS Department of Health Information on the Palliative Care Information Act

The New York State Department of Health has information (DOH) on its website on the PCIA. This includes Questions and Answers about Palliative Care, Hospice, and the Palliative Care Information Act and a list of Resources for Practitioners, http://www.health.ny.gov/professionals/patients/patient_rights/palliative_care/. It provides a good deal of useful information and should be a helpful guide to health care and legal practitioners. DOH has informed hospitals and nursing homes about the law and has sent the information on its website to them and to a mailing list of associations and societies. However, it is likely that many individual health care practitioners will not be informed or timely informed about the PCIA. Health care attorneys are urged to find out whether your health care practitioner colleagues know about the PCIA and the information available from the DOH and to inform those who do not.

Counseling

The PCIA definition of attending health care practitioner is clear. One or more physicians or nurse practitioners might have primary responsibility for the care and treatment of the patient so that each of them would have responsibility to provide information and/or counseling to the surrogate who agrees to accept it. Physicians having different specialties might equally be involved with a patient's care. There is no bar to the involvement of any practitioner or specialist who is acting as an attending practitioner whom a surrogate wishes to access for the counseling and information under the PCIA. Any such bar would run counter to the legislative goals and intent of the PCIA and may result in a contraction of information on palliative care and end-of-life options to surrogates of patients who are terminally ill.

In most situations there probably will and should be more than one information/counseling meeting. For example, the practitioner may offer to provide information and counseling during one conversation and, if the surrogate agrees, they may jointly decide to have a second meeting to discuss specific options. The surrogate, who will usually be a family member, may wish to have others family members attend.

Best practice will normally require continuing conversations as the patient's disease worsens and condition changes. Appropriate options to discuss initially with a surrogate may be different than appropriate options to discuss later as the trajectory of the disease or illness progresses. As a patient's condition changes and worsens, surrogates who have initially declined should again be offered information and counseling.

If one health care professional has had a discussion with the surrogate, another health care professional now involved as an attending may still be obligated to have a discussion with the surrogate. If a physician asks "have you had a conversation about this" and the surrogate responds affirmatively, the physician should ask if the surrogate would like to discuss anything relevant to palliative care and end-of-life options. The surrogate could agree or decide to have continued discussions only with the health care professional with whom the surrogate first talked.

Documentation

Documentation of the provision of any information and/or counseling should always be placed in the patients' medical record under the PCIA so that all practitioners working with patients will be informed of what has transpired. Where more than one health care practitioner is involved in providing the information/counseling, documentation is essential so that each practitioner knows and understands what others have done and said and that, where possible, there is consistency.

Documentation by a health care professional of a meeting with the surrogate to discuss palliative care/end-of-life options does not diminish the obligation of that same health care professional to have continuing discussions, as appropriate with the surrogate, all of which are properly documented.

Conclusion

The need for and the importance and benefits of the Palliative Care Information Act, a model for the nation, are clear. Physicians are not spending enough time having discussions with their patients about end-of-life care and explaining fully the options available to patients early enough in the course of illness. Yet patients generally do, and presumably surrogates will, want to know the diagnosis, prognosis, treatment alternatives and the risks and benefits of those options so that they can make informed

decisions. When physician-patient communications do take place, the quality of lives of patients improves, patients are referred to hospice earlier, patients live longer, their wishes are more often respected and costs are reduced. If the PCIA is implemented as intended, surrogates should be able to make informed decisions about palliative care and end-of-life options for patients who lack decision making capacity.

Health care attorneys can and should play an important role to ensure successful implementation of the Palliative Care Information Act generally, and particularly in conjunction with the Family Health Care Decisions Act.

Endnotes

1. 2010 Laws on NY, Ch. 331; NY Public Health Law §2997-C.
2. NY Public Health Law, Article 29-CC, §2994-d3(c).
3. NY Public Health Law, Article 29-D, §2997-c2.
4. NY Public Health Law, Article 29-D, §2997-c2. There has been some confusion about what the attending health care practitioner must do. The attending health care practitioner must offer to provide information and counseling, which is not the same as being required to provide it, unless the patient or here the surrogate wants it. The patient, or here the surrogate, may and usually will want the information and counseling but has the right to refuse it.
5. NY Public Health Law, Article 29 D, §2997-c2.
6. NY Public Health Law, Article 29 D, §2997-c2, c3.
7. NY Public Health Law, Article 29 D, §2997-c2.
8. *Id.*
9. *Id.*
10. Alexi A. Wright, et al., "Associations Between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment," *JAMA*, 2008;300(14):1665-1673.
11. http://www.nyhealth.gov/statistics/facilities/hospice/utilization_and_cost/2007/.
12. T.R. Fried, et al., "Prognosis communication in serious illness: Perceptions of Older Patients, Caregivers, and Clinicians. Journal of the American Geriatrics Society. 2003. 51:1398-1403.
13. A. Bhatnagar, et al., "What do Patients want from Their Radiation Oncologist? Final Results from a Prospective Randomized Trial," Radiation Oncology Volume 75, Number 3, Supplement, 2009.
14. Alexi A. Wright, et al., "Associations Between End-of-Life Discussions, Patient Mental Health, Medical Care Near Death, and Caregiver Bereavement Adjustment," *JAMA*, 2008;300(14):1665-1673.
15. Jennifer S. Temel, et al., "Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer," New England Journal of Medicine, 363; 8, 2010.
16. Jennifer W. Mack, et al., "End-of-Life Discussions, Goal Attainment, and Distress at the End of Life: Predictors and Outcomes of Receipt of Care Consistent With Preferences," .J Clin. Oncol. 28:1203-1208 (2010).
17. Baohui Zhang, et al., "Health Care Costs in the Last Week of Life Associations With End-of-Life Conversations," Arch. Intern. Med. 2009; 169(5):480-488.

David C. Leven, J.D., is the Executive Director of Compassion & Choices of New York. He is an advocate for improved palliative care and end-of-life care and decision making. The Palliative Care Information Act was introduced at his urging as was the Palliative Care Education and Training Act, enacted in 2007, to improve medical school and post-medical school training on pain management, palliative care and end-of-life care. Mr. Leven lectures on end-of-life issues to health care professionals, lawyers, seniors and students.

NEWS flash

What's Happening in the Section

Francis J. Serbaroli Elected Chair of Section

At its Annual Meeting, the Section elected the following officers for one year terms beginning June 1, 2011.

- Francis J. Serbaroli, Chair
- Marcia Smith, Chair-Elect
- Ellen Weissman, Vice-Chair
- Kathleen Burke, Secretary
- Margaret Davino, Treasurer

The new Chair, Francis J. Serbaroli, is a shareholder in the Health & FDA Business Practice of Greenberg Traurig's New York office. Frank has three decades of experience in the health care industry. Frank served as a member of the New York State Public Health Council (now the Public Health and Health Planning Council) from 1995 to 2010, for most of that time as the council's vice chairman. His government experience also includes three years as an Assistant Attorney General of the State of New York. He writes a regular health law column for the *New York Law Journal* and teaches and lectures on health care, corporate governance and not-for-profit issues. He also writes a regular column, *In the New York State Agencies*, for the NYS Bar Association *Health Law Journal*.

Upcoming Events

- **Health Care Decision Making.** A CLE program on "Health Care Decision Making: Implementation of the Family Health Care Decisions Act, Recent Developments and Ethical Considerations" will be held in two locations:
  - Albany—Friday, May 6, 2011
  - New York City—Friday, May 13, 2011

  The program will cover the FHCDA, the Health Care Decisions Act for Persons with Mental Retardation, Do-Not-Resuscitate statutes, and mental health issues. It will also consider special issues in consent, such as consent to organ donation, reproductive procedures and human subject research, and consent for children and older minors.

  The program is co-chaired by Lawrence Faulkner of Westchester Association for Retarded Citizens and Tracy Miller of Cadwalader, Wickersham and Taft.

- **Basic Health Law for the Non-Health Lawyer**. The Committee on Fraud, Abuse and Compliance will be presenting this webinars on May 3, 2011, from 12:00 p.m. to 1:30 p.m., Alexander Bateman, Jr. and David Daniels, will present, Melissa Zambri will moderate.
- **Self-Disclosure: Practical Tips and Stories**. The Committee on Fraud, Abuse and Compliance will be presenting this webinar on September 22, 2011, from 12:00-1:30 p.m. Catherine Diviney and Jeffrey Sherrin will present; Melissa Zambri of Hiscock & Barclay (Albany) will moderate.

Committee Activities

- **Public Health Committee Looking into Accountable Care Organizations.** Public Health Committee Chair Julia Goings-Perrot reports that the committee is focusing on accountable care organizations and their distinguishing element of public health considerations. In particular:
  - Maureen Bisognano, President and CEO of the Institute of Health care Improvement, was a guest speaker on a committee conference call on February 11. Ms. Bisognano worked closely with her predecessor, Donald Berwick, M.D. (who is now Director of CMS), in developing the theoretical underpinnings of ACOs.

– Assembly Health Chair Richard N. Gottfried spoke with the Committee on February 27 regarding a legislative proposal to establish standards for ACOs.

– Committee members are now reviewing and draft legislation on ACOs.

Ms. Goings-Perrot stated that "The committee is looking forward to continuing to educate ourselves and serving as a liaison and resource for policy-makers and stakeholders in understanding and implementing ACOs."

- **Call for Vice-Chairs.** Section Chair Ari Markenson has asked each committee to identify a person to be Vice-Chair, both to help the committee chair, run meetings in the absence of the chair, and help promote an orderly turnover of committee leadership positions. Section members who are interested in serving as Vice-Chair should contact the Chair of the applicable committee.

Recent Events

- **Annual Meeting.** The Section's Annual Meeting was held at the Hilton New York in New York City on January 26, as part of the NYSBA Annual Meeting. The Section offered a day-long program, "Selected Developments in Health Law: The Year in Review." Audience surveys indicated that participants were very pleased with the presentations. The program was co-chaired by Tracy Miller of Cadwalader, Wickersham & Taft, and Kelly Prieg-nitz of Benesch, Friedlander, Coplan & Aronoff, LLP.

  NYS Assembly Health Committee Chair Richard N. Gottfried was the luncheon speaker at the meeting. Assemblyperson Gottfried noted the landmark passage of the Family Health Care Decisions Act in 2010 and thanked the Section for its critical support for that bill. He then spoke about the difficult budget ahead, and about health care reform. He noted that he was considering the need to introduce legislation relating to Accountable Care Organizations.

Recent Supraspinatus Topics

- NY Hospital Data Theft May Affect Records of 1.7 Million
- Long Island College Hospital in Brooklyn May Close—NYTimes.com
- NY Medicaid Reform Task Force Rolling Up Sleeves
- Legislative Session up and running
- Budget Presentation planned for 2/1 at 1pm
- HANYS Report Details Physician Shortage
- US-China int'l PPP in health care sector
- NYC Ambulance Fee Stirs Up a Brouhaha
- Feds Accuse NYC Of Medicaid Fraud, Seek Tens of Millions, Triple Damages
- Electronic Certificate of Need System Launched
- Community General Teeters, Looks to Upstate
- Governor Creates Medicaid Redesign Team
- Drug price reporting practices
- Cuomo Announces New Health Commissioner
- Drug regulation and investments in it—the *Matrixx* case

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

Section Committees and Chairs

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

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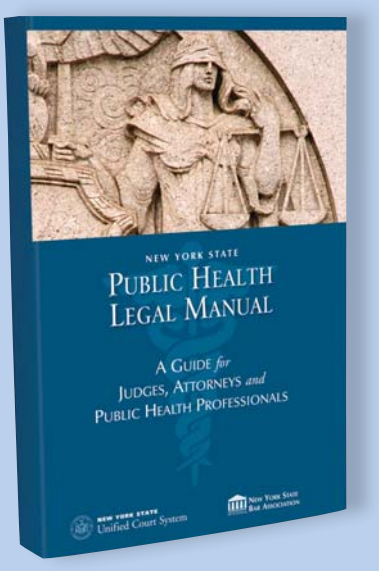

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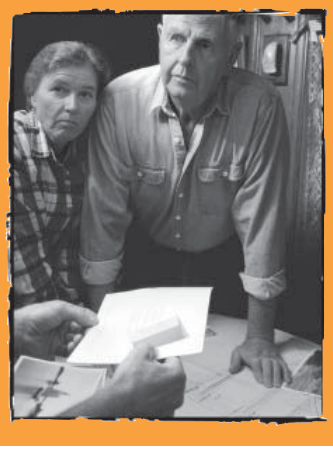

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