

# Health Law Journal



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

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Mary Beth Morrissey and Bruce Jennings,  
Special Edition Editors

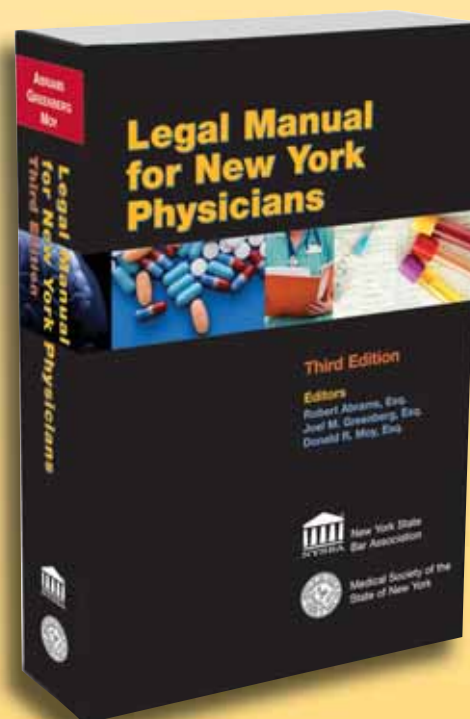
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# **HEALTH LAW JOURNAL**

**SPRING 2012**

**Vol. 17, No. 2**

THE HEALTH LAW SECTION  
NEW YORK STATE BAR ASSOCIATION

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**"Gaze Maternel de L'Enfant" by Mary Beth Morrissey, 1977**  
 Selected to recognize public health achievements in maternal child health.

# A Message from the Section Chair

Dear Section Members:

It is hard for me to believe that my term as Section Chair is coming to an end shortly. The last year has flown by, but with the help of so many Section members much as been accomplished. As I noted in my last column, our committees have been re-organized, we have presented a number of outstanding programs, and our membership continues to grow. This Summer, we will sponsor our first minority student internship with a \$3,000 stipend. The internship will take place at the general counsel's office at Catholic Health Services of Long Island, and we are currently contacting law schools to solicit candidates. Our thanks to Section Members Mickey Kranz, Lisa Hayes and Karen Gallinari for organizing our internship program.

The Health Law Section has grown into one of the larger Sections of our Association, and the time has come to do some strategic planning for our Section's future.



Accordingly, I am in the process of appointing a Strategic Planning Task Force to look at what our Section should be doing over the next several years. Among the activities that I would like to see our Section get involved in is a mentoring program in which law students and younger lawyers interested in pursuing a career in health law would be paired with veteran health law practitioners who can provide them with career guidance as well as advice on researching and addressing substantive health law issues. The work of the Strategic Planning Task Force will continue for about the next two years, and the Task Force's recommendations will be presented to the Executive Committee and then the full Section. Anyone interested in working on the Task Force should contact me (serbarolif@gtlaw.com) or incoming Section Chair Ellen Weissman (eweissman@hodgsonruss.com).

It has been an honor to serve as your Section Chair, and I want to thank our Executive Committee and Section Officers for all their help during my term. It is a great team, and I look forward to continuing to contribute to our Section's work.

**Cordially,  
Francis J. Serbaroli**

## Request for Articles



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

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*Articles should be submitted in electronic document format (pdfs are NOT acceptable), along with biographical information.*

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# In the New York State Courts

By Leonard M. Rosenberg

## Court Holds that Insurance Law § 3224-a—The Prompt Pay Law—Confers a Private Right of Action Upon Patients and Health Care Providers

*Maimonides Med. Ctr. v. First United Am. Life Ins. Co.*, 941 N.Y.S.2d 447 (Sup. Ct., Kings County, 2012). Defendant, First United American Life Insurance Company (“First United”), moved to dismiss Maimonides Medical Center’s (“Maimonides”) complaint, in which Maimonides alleged breach of contract, violation of Insurance Law § 3224-a (the “Prompt Pay Law”) and/or unjust enrichment, in connection with six patients that Maimonides treated, each of whom were covered under one of First United’s supplemental Medicare insurance plans. In support of its motion, First United claimed that there was no express or implied private right of action under the Prompt Pay Law. The Court held that a private right of action exists under the Prompt Pay Law.

The Prompt Pay Law provides that when an insurer is clearly liable to pay a health care claim, the health care provider or patient must be paid within thirty (30) days of an electronically transmitted claim, or within forty-five (45) days of receipt of a claim transmitted by any other means. When liability is not reasonably clear, the insurer must pay the undisputed amount within the thirty (30) or forty-five (45) days, and must provide either written notification specifying the reasons why it is not liable for the remaining balance of the claim, or a written request for additional information necessary to determine liability. An insurer that fails to abide by these standards will be obligated to pay the full amount of the claim plus interest of 12%, or the corporate tax rate set by the Commissioner of Taxation and Finance, whichever is greater, to the health care provider or person submitting the claim. In



addition to being liable for full payment plus interest, the Prompt Pay Law authorizes administrative enforcement by allowing the Superintendent of Insurance (“Superintendent”) to investigate violations and assess civil penalties both on his own accord and upon complaint from an individual claimant. The issue before the court was whether the Prompt Pay Law conferred a private right of action so that an individual claimant or provider could sue an insurer.

The essential factors the Court considered in determining whether the Prompt Pay Law had an implied private right of action were: (1) whether the plaintiff is one of the class for whose particular benefit the statute was enacted; (2) whether recognition of a private right of action would promote the legislative purpose; and (3) whether creation of such a right would be consistent with the legislative scheme.

The Court found that Maimonides was part of the class for whose benefit the statute was enacted, because the purpose of the Prompt Pay Law was to protect health care providers and patients against insurance companies that failed to pay claims in a timely fashion. Consistent with that purpose, Maimonides claimed that it was not paid for services rendered within the statutory time period, and thus was a member of the class that the Legislature intended to benefit in passing the Prompt Pay Law.

Likewise, the Court found that a private right of action would promote the legislative purpose of the statute. The Court noted that the legislative intent of the statute was to prevent

delay in the payment of health care claims. Allowing individual claimants to seek full payment of their claims plus interest directly through the court advances the prompt payment of compensation and deters unwarranted delay, and thus promotes the legislative purpose of the statute.

Finally, in finding that the creation of a private right of action would be consistent with the legislative scheme, the Court examined the plain language and legislative intent of the statute. Paragraph (c)(2) of the statute, which enumerates the power of the Superintendent, expressly provides that nothing in the section shall limit, preclude, or exempt an insurer from payment of a claim. From the plain language of the statute the Court determined that paragraph (c)(1) expressly conferred a private right of action, and paragraph (c)(2) did nothing to remove that private right. Additionally, in considering the legislative intent of the statute, the Court stated that while the statute empowered the Superintendent to investigate and impose fines, the primary purpose of the legislation was to provide a statutory right to the individual patient or provider to obtain payment of claims for health care services.

Appellate Division Holds That Drug Testing Laboratory Can Be Held Liable in Tort to Subject of Drug Test for Failing to Use Reasonable Care Despite Absence of Contractual Privity

*Landon v. Kroll Laboratory Specialists, Inc.*, 91 A.D.3d 79, 934 N.Y.S.2d 183 (2d Dep’t 2011). Plaintiff was required to submit to drug testing by the terms of his criminal probation. He sued the drug testing laboratory for negligently analyzing his oral test sample, which resulted in an erroneous report that he tested positive for drug use. The Appellate Division, Second Department, held that a drug

testing laboratory can be liable for negligently testing a test subject's biological sample despite the fact that there was no formal contractual relationship between the test subject and the drug testing laboratory.

Defendant drug testing laboratory entered into a contract with the Orange County Probation Department to analyze probationers' oral test samples for the presence of controlled or illicit substances. After Plaintiff was convicted of forgery and sentenced to a five-year-term of probation, Plaintiff was required to submit an oral test sample to his probation officer to determine whether Plaintiff was complying with the terms of his probation. The Orange County Probation Department sent Plaintiff's sample to Defendant to determine whether it tested positive for any drug use. On this same day, Plaintiff also obtained an independent blood test which revealed that Plaintiff's blood sample was negative for illicit or controlled substances.

When Defendant received Plaintiff's test sample a few days later, it tested the sample in accordance with its standard policy and practice, and determined that it was positive for marijuana. Defendant thereafter informed the Orange County Probation Department of the results in a written report. As a result of the report, Plaintiff's probationary sentence was extended and Plaintiff was compelled to appear multiple times in court to avoid incarceration.

In his complaint, Plaintiff claimed that Defendant utilized a screen test cutoff level that was significantly lower than the industry-wide standard for forensic drug testing, and that Defendant never confirmed the results through a gas chromatography mass spectrometry test, which Defendant is required to undertake as a holder of a New York State Department of Health Laboratory Permit for Comprehensive Forensic Toxicology. Defendant moved to dismiss the complaint for failure to state a cause of action, and the Supreme Court

granted Defendant's motion and dismissed the complaint pursuant to CPLR 3211(a)(7).

The Appellate Division reversed. In reaching its decision, the Court considered the respective duties imposed in tort and contract law, recognizing that "[a] person is not necessarily insulated from liability in tort merely because he or she is engaged in performing a contractual obligation." Indeed, the Court reasoned that "the very nature of a contractual obligation, and the public interest in seeing it performed with reasonable care, may give rise to a duty of reasonable care in performance of the contract obligations, and the breach of that independent duty will give rise to a tort claim." Relying on the Restatement of Torts, the Court also held that whether the laboratory exercised a reasonable degree of care is "established through evidence of the general customs and practices of others who are in the same business or trade as that of the alleged tortfeasor."

Applying this reasoning to the case before them, the Court held that Plaintiff adequately alleged that Defendant undertook to perform forensic toxicology testing, was negligent in the performance of such undertaking, and failed to exercise reasonable care under the circumstances as demonstrated by the general customs and practices of others in the field of forensic toxicology testing. The only question that remained was whether Defendant owed a duty of care to Plaintiff.

The Court held that the existence and scope of an alleged tortfeasor's duty is a "legal, policy-laden declaration reserved for Judges" that is defined neither by foreseeability of injury nor privity of contract. Nonetheless, because tort law is, at its base, a means of apportioning risk and allocating the burden of loss, the Court recognized that it is sometimes necessary to invoke a concept of privity of contract "as a means of fixing fair, manageable bounds of liability."

Under the circumstances of this case, the Court found that the "prospect of limitless liability is extremely small." The Court reasoned that Defendant's alleged duty of care relates only to a class of specific and readily identifiable individuals whose test samples were analyzed for a contractual purpose, the nexus between Defendant and the test subject was not attenuated or remote, and imposing a duty on Defendant would not result in a "crushing burden of limitless liability."

Further, the Court held that the permanent and devastating effects that a positive toxicology result may have on an individual outweigh the burden of imposing liability on a drug testing laboratory. The Court also recognized that drug testing has become a multi-million dollar growth industry and that laboratories are willing to skip costly double-checking procedures in order to offer cheaper testing at the cost of accuracy and to the detriment of the non-contracting test subject. Finally, the Court held that many other states have already recognized a duty running from a drug testing laboratory to the non-contracting test subject, and found persuasive the federal line of cases which have concluded that New York courts would recognize such a duty under state law. As a result, the Court held that despite the absence of a formal contractual relationship between Plaintiff and Defendant, Plaintiff's complaint alleged a sufficient cause of action for negligence to withstand Defendant's motion to dismiss.

#### **Fourth Department Holds That OMIG Cannot Exclude a Physician From the Medicaid Program Solely Based Upon an OPMC Consent Order, When Those Sanctions Do Not Preclude the Physician From Practicing Medicine**

*Matter of Koch v. Sheehan*, 95 A.D.3d 82, 940 N.Y.S.2d 734 (4th Dep't, 2012). Petitioner, a physician, brought an Article 78 action against the Respondent, the New York State Medicaid Inspector General, to chal-



lenge a determination of the Office of the Medicaid Inspector General (“OMIG”), excluding him from participation in the New York State Medicaid Program. OMIG based its decision to exclude Petitioner upon a Consent Order that Petitioner signed after New York’s Office of Professional Medical Conduct (“OPMC”) found that he had failed to meet the accepted standards of care with regard to his treatment of two non-Medicaid patients. In the Consent Order, Petitioner pleaded “no contest” to these charges, and agreed to be placed on probation and to comply with various other conditions. Nothing in the Consent Order precluded Petitioner from practicing medicine. However, after OMIG reviewed the Consent Order, it notified Petitioner that he would be excluded from participation in the Medicaid program, and therefore could not receive reimbursement for treating Medicaid patients. OMIG did not conduct an independent investigation of Petitioner, and based its decision solely on the contents of the Consent Order.

The Supreme Court, Erie County vacated OMIG’s determination and reinstated Petitioner to the Medicaid program, retroactive to the date of his exclusion. The Appellate Division upheld the lower court’s decision, holding that OMIG’s exclusion of Petitioner from the Medicaid program was arbitrary and capricious.

First, the Court held that the Petitioner could pursue his claims despite his apparent failure to timely exhaust his administrative remedies. Subsequent to commencing his Article 78 action, Petitioner had submitted an administrative appeal to OMIG, but OMIG had rejected the appeal as untimely—therefore, Petitioner’s administrative remedies had not been exhausted. The Court, however, held that the exhaustion rule should not be inflexibly applied if it is clear that an administrative appeal would not succeed, and based upon Respondent’s position in the litigation, it was apparent that Petitioner’s administra-

tive appeal would have been denied. The Court also noted with suspicion that Respondent had not asserted the exhaustion issue in the litigation, raising questions about whether OMIG’s dismissal of Petitioner’s appeal had been appropriate.

The Court then upheld the lower court’s decision to vacate the OMIG exclusion and reinstate Petitioner to the Medicaid program. In doing so, the Court relied on two prior decisions: *Matter of Mihailescu v. Sheehan*, 25 Misc.3d 258, 885 N.Y.S.2d 386 (Sup. Ct. N.Y. County 2009) and *Napoli v. Sheehan*, No. I2009-14524 (Sup. Ct. Erie County May 25, 2010). In both of those cases, the courts held that OMIG could not exclude a physician from the Medicaid Program merely based upon uncontested OPMC sanctions, if those sanctions did not preclude the doctor from practicing medicine. If the OPMC, which had conducted a thorough investigation of the physician’s alleged transgressions, determined that the physician could continue to practice medicine, then OMIG, which conducted no such investigation, had no basis to assert that the physician could not safely treat Medicaid patients. The court in *Napoli* further observed that a physician would likely not enter into a Consent Order, giving up his opportunity to contest OPMC’s charges, if doing so meant that he would not be able to continue to practice medicine. See *Koch*, 2012 WL 975612 at \*5 (citing *Napoli*).

Applying these cases, the Court held that OMIG’s decision to exclude Petitioner from the Medicaid Program was arbitrary and capricious, because the penalty imposed by OPMC in the Consent Order, which formed OMIG’s sole basis for Petitioner’s exclusion, did not include suspension. To hold otherwise, said the Court, would lead to the irrational result of allowing Petitioner to treat non-Medicaid patients but precluding him from treating Medicaid patients. The Court also noted that Petitioner likely would not have

agreed to the Consent Order if he had known that it would effectively preclude him from practicing medicine.

The Court further observed that not only would Petitioner’s exclusion from treating Medicaid patients be irrational, but it would also be contrary to legislative intent. Quoting *Mihailescu*, the Court stated that the Legislature tasked OPMC with ensuring the safety of all patients (including Medicaid patients), and it was not the Legislature’s intent that OMIG second-guess OPMC, but rather that OMIG defer to OPMC’s findings. In this case, OMIG had no independent basis for excluding Petitioner from the Medicaid Program, and therefore its reliance on the Consent Order was arbitrary and capricious.

#### **Public Health Law § 2808(5)(c), Which Requires Prior Consent From DOH to Withdraw Equity Exceeding 3% of a Nursing Home’s Annual Revenue, Held Unconstitutional**

*The Brightonian Nursing Home v. Daines*, 93 A.D.3d 1355, 941 N.Y.S.2d 396 (4th Dep’t, 2012). Plaintiffs, nursing homes and rehabilitation centers in New York, commenced a hybrid Article 78 proceeding and declaratory judgment action to challenge the constitutionality of the Public Health Law (“PHL”) § 2808(5)(c). The Supreme Court, Monroe County declared PHL § 2808(5)(c) unconstitutional. The Appellate Division, Fourth Department unanimously affirmed.

PHL § 2808(5)(c) prohibits private residential health care facilities, *i.e.*, nursing homes, from withdrawing equity or transferring assets that in the aggregate exceed 3% of their total annual revenue for patient care services, without the prior written approval of the Commissioner of Health (the “Commissioner”). In reviewing requests by private residential health care facilities for approval, the statute permits the Commissioner broad discretion to consider, among other reasons, “such other factors as the Commissioner deems appropriate.” It was this “catchall” provision of PHL

§ 2808(5)(c) that plaintiffs challenged as vague and improperly delegating legislative authority to the Commissioner. The Appellate Division agreed that the catchall provision of the statute provides no standards to guide the Commissioner in determining what factors are appropriate for consideration. Nor does the statute provide sufficient standards to permit nursing home owners and operators reasonable certainty as to what other factors will be considered. As a result, the Commissioner is left with unfettered discretion to consider any undefined factors, which the Court held amounted to an unconstitutional delegation of legislative authority.

The Appellate Division rejected Defendants' arguments that the catchall provision could be struck and the remaining section of PHL § 2808(5)(c) left intact, finding that the statute in its entirety was not reasonably related to the government purpose underlying its enactment. The Court also ruled that the remaining provisions of PHL § 2808(5), including, *inter alia*, subsections (a) and (b), provide sufficient protection to nursing home residents and the public from excessive withdrawals of equity from nursing home owners and operators. Subsection (a) requires prior consent from the Commissioner for an equity withdrawal that would create or increase a negative net worth; subsection (b) requires prior written notice to the Commission (rather than prior consent) of an equity withdrawal in excess of 3% of annual revenues.

#### **Federal District Court Dismisses Plaintiff's Common Law and Statutory Claims Against Corporate Affiliates of a Medical Clinic for Disclosure of Confidential Health Information**

*John Doe v. Guthrie Clinic, Ltd., et al.*, 2012 WL 531026 (W.D.N.Y., Feb. 17, 2012). Plaintiff, who was being treated for a sexually transmitted disease ("STD") at Guthrie Clinic Steuben (the "clinic"), a private medical clinic in Corning, New York, sued Defendants (collectively "Guthrie")

for breach of fiduciary duty, breach of contract, negligent hiring, negligent and intentional infliction of emotional distress, and statutory violations of New York Public Health Law § 2803-c, New York Public Health Law § 4410, and New York Civil Practice Law and Rules § 4504. Defendants successfully moved to dismiss Plaintiff's complaint in its entirety.

Plaintiff alleged that while he was waiting in the clinic for treatment of his STD, Magan Stalbird, a nurse employed by the clinic ("Stalbird"), recognized the Plaintiff as the boyfriend of her sister-in-law, Jessica, and accessed the Plaintiff's medical records for determining the purpose of his visit. Plaintiff further alleges that Stalbird then sent at least six (6) text messages to Jessica informing her of the Plaintiff's medical condition. Jessica then forwarded Stalbird's text messages to the Plaintiff. Five days after the incident, after Plaintiff complained to the Defendants, corporate affiliates of the clinic, about Stalbird's actions, she was fired. Following Stalbird's termination, Jessica allegedly received a text message from her brother, Stalbird's husband, threatening the Plaintiff's life. Thereafter, Dr. Joseph A. Scopelliti, the President and CEO of Guthrie Clinic, Ltd., a named defendant, sent a letter to the Plaintiff explaining that there had been a breach of the Plaintiff's confidential health information, that appropriate disciplinary actions had been taken, and that steps had been taken to prevent a similar breach from occurring in the future. Plaintiff then commenced this action against the Defendants, in which neither Guthrie Clinic Steuben nor Stalbird were named as defendants.

Plaintiff claimed that under the theories of vicarious liability and *respondeat superior* the Defendants, as fiduciaries, owed a duty of confidentiality to him, and breached this duty by disclosing his confidential health information. The Court disagreed with the Plaintiff, holding that Stalbird's disclosure of the Plaintiff's

confidential health information was outside the scope of her employment. Specifically, the Court noted that Stalbird's actions were motivated by personal reasons, and that there is no *respondeat superior* liability for torts committed for personal motives unrelated to the furtherance of the employer's business.

Furthermore, the Court refused to apply a strict liability standard in cases such as this, where a corporate defendant's employee has, without authorization, violated the duty of confidentiality owed by the employer. In doing so, the Court recognized that the New York Court of Appeals had also refused to extend the strict liability standard in a similar case, and stated that whether strict liability should be imposed in situations such as these is a question properly left to the legislature. See *N.X. v. Cabrini Medical Center*, 97 N.Y.2d 247, 739 N.Y.S.2d 348 (2002).

The Plaintiff further alleged that the Defendants breached a duty of confidentiality embodied in an implied contract when Stalbird disclosed his personal health information. The Court, in applying the same logic as with Plaintiff's breach of fiduciary duty claim, dismissed the breach of contract claim, stating that Stalbird's actions could not be imputed to the Defendants as she was acting outside the scope of her employment.

The Court also dismissed Plaintiff's statutory claims. The Court dismissed Plaintiff's claim that Defendants violated New York Public Health Law § 2803-c, finding that the named Defendants did not provide "health related service" as required by the statute, and thus the statute was inapplicable to the Defendants. In dismissing the Plaintiff's claims that Defendants violated New York Public Health Law § 4410, and New York Civil Practice Law and Rules § 4504, the Court held that neither statute provided for a private cause of action for the unauthorized disclosure of confidential health information.

## New York Court of Appeals Held That Emergency Room Psychiatrist Had Standing to Seek Patient's Involuntary Commitment and Was Not Required to Follow Special Emergency Commitment Procedures Under Mental Hygiene Law § 9.39

*Rueda v. Charmaine D.*, 17 N.Y.3d 522, 934 N.Y.S.2d 72 (N.Y. 2011). Patient Charmaine D. was brought to the emergency room at Jacobi Medical Center and seen by an attending psychiatrist. The attending psychiatrist concluded that the patient was “currently paranoid, grandiose with decreased insight and judgment, poor impulse control, unable to care for self” and a potential danger to self and applied to have her involuntarily admitted to a hospital pursuant to Mental Hygiene Law § 9.27. After the patient was transferred to Montefiore North Medical Center and the Director of the Psychiatry Department of the facility applied for a 30 day retention order, Charmaine moved to dismiss the retention proceedings on the grounds that her original commitment was defective because the attending psychiatrist was not a proper applicant under Mental Hygiene Law § 9.27 and that the only option available to the Jacobi emergency room doctors was to seek her commitment under Mental Hygiene Law § 9.39.

Mental Hygiene Law § 9.27 lists 11 categories of applicants who have standing to involuntarily commit a patient including “a qualified psychiatrist who is either supervising the treatment of or treating such person for mental illness.” The patient argued that the words “treatment” and “treating” should not include the relatively brief physician-patient relationship that exists in an emergency room but should require that all applicants have or supervise a close relationship with the person proposed for commitment. The Court of Appeals, however, disagreed with the patient’s interpretation of the statute finding that “the broader reading of the statute will better serve its purpose.” The Court of Appeals ex-

plained that it viewed the list of proposed applications in § 9.27 as “a legislative attempt to describe categories of people likely to have a sincere and legitimate interest in the well-being of the person they are seeking to have committed” but that “the relationship need not be an intimate one.” In the Court’s view “[t]he main point of the list, as we interpret it, is to exclude those whose lack of a significant relationship with the allegedly mentally ill person might create a suspicion that they are simply meddling, or acting out of spite.” Based on that interpretation, the Court of Appeals concluded that “[e]mergency room psychiatrists are unlikely so to abuse the § 9.27 commitment process” and, thus, had standing to seek involuntary commitment of the patient.

The second issue addressed by the Court of Appeals was whether Charmaine could have properly been committed under Mental Hygiene Law § 9.27 when the prerequisites of Mental Hygiene Law § 9.39 are met. Section 9.27 describes the general procedure for involuntary hospital admissions whereas § 9.39 describes a special procedure for emergencies.

Section 9.27 is entitled “Involuntary admission on medical certification.” It provides a method by which the director of a hospital “may receive and retain therein as a patient any person alleged to be mentally ill and in need of involuntary care and treatment.” An admission under § 9.27 requires the execution of three separate documents: an “application” and “certificate of two examining physicians.” It also requires that when the patient is brought to a hospital, the director of that hospital “shall cause such person to be examined forthwith by a physician who shall be a member of the psychiatric staff of such hospital other than the original examining physician,” and authorizes admission “if such person is found to be in need of involuntary care and treatment.”

Section 9.39, entitled “Emergency admissions for immediate observation, care, and treatment,” is designed

for emergency situations, in which § 9.27’s procedures might not be adequate to protect the patient or the public. Section 9.39 can be employed only where a person is “alleged to have a mental illness for which immediate observation, care, and treatment in a hospital is appropriate.” Further, § 9.39 can be employed only where the alleged mental illness “is likely to result in serious harm” to the mentally ill person or others.

The Appellate Division dissent agreed with Charmaine that § 9.27 commitment would not be available under those circumstances; however, the Court of Appeals did not. The Court of Appeals reasoned that “[i]t does not make sense that those seeking commitment should be *required* to use the emergency procedure where the nonemergency procedure is adequate.”

## New York Courts and Administrative Agencies Cannot Declare New Gender of Resident Born Out of State After Irreversible Gender Reassignment Surgery

*A.B.C. v. N.Y.S. Dep’t of Health*, 939 N.Y.S.2d 691 (Supreme Court, Queens County 2012). Petitioner, a resident of New York State born in California, commenced a special proceeding in Queens County Supreme Court in which he sought declaration of his gender following irreversible gender reassignment surgery from female to male. He planned to submit such a court order declaring his gender to be a male to the State of California to facilitate a change in the “sex” designation on his California birth certificate to male. The petitioner previously obtained an order from a Supreme Court Justice of another New York State county court, pursuant to Civil Rights Law article 6, authorizing a change of name, and the court stated that the petitioner’s California birth certificate was allegedly reissued by the State of California to reflect the court-ordered change of name.

The court denied the petition against the New York State Depart-



ment of Health (“NYSDOH”), recognizing that the NYSDOH had no duty, responsibility, or stake in the petitioner’s application because it is only responsible for the registration of births occurring in New York State outside of New York City, and that petitioner implicitly conceded as much by not seeking relief from the NYSDOH.

Addressing this issue of first impression, the court stated that it lacked a statutory basis to entertain the petitioner’s request for an order recognizing his gender reassignment surgery and declaring him to be of the male gender. The court noted that a declaratory judgment action would have been the appropriate type of action procedurally, but declined to convert the action based on its conclusion that there was no adverse party, and thus no justiciable controversy, and that such a conversion would be futile because the court could not, in any case, provide the petitioner with the relief he sought.

#### **Appellate Division Holds That Children Stated Valid Cause of Action for Violation of Right of Sepulcher**

*Henderson v. Kingsbrook Jewish Medical Center*, 91 A.D.3d 720, 936 N.Y.S.2d 318 (2d Dep’t 2012). Plaintiffs, the children of their deceased father, filed a complaint against the Hospital, alleging a violation of the their right of sepulcher. Plaintiffs claimed that the Hospital failed to release their father’s body to their chosen funeral home until three days after his death, despite their inquiries and efforts to release the body earlier. The Hospital moved to dismiss the complaint for failure to state a cause of action pursuant to CPLR 3211(a) (7). The Supreme Court, Kings County, granted the Hospital’s motion without explanation.

The Appellate Division, Second Department, reversed. Acknowledging that New York has “long recognized the interest of a decedent’s next

of kin in the remains of their decedent,” the Appellate Division held that Plaintiffs’ allegation that the Hospital interfered with their “absolute right to the immediate possession of [their father’s] body for preservation and burial” was sufficient to state a cause of action to survive the Hospital’s motion to dismiss. In reaching its decision, the Appellate Division held that although the Hospital’s delay in releasing the decedent’s body may ultimately be determined to have been reasonable and proper under the circumstances, “[w]hether [the] plaintiff can ultimately establish [his] allegations is not part of the calculus in determining a motion to dismiss [made pursuant to CPLR 3211(a)(7)].” Accordingly, the Appellate Division concluded that the Supreme Court erred in dismissing the Plaintiffs’ cause of action for violation of their right of sepulcher.

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

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# In the New York State Legislature

By James W. Lytle

## *Challenging Times for Not-for-Profit Health Care in New York*

New York State has had a well-earned reputation for favoring not-for-profit sponsorship of health care and other human services providers in New York: for-profit entities, especially publicly traded organizations, have long complained that they were not welcome in New York, thanks to laws and policies designed to favor tax-exempt not-for-profit health care organizations.

The “honeymoon” for not-for-profit entities in New York may be over. A number of recent policies and laws under recent consideration may be viewed as ushering in a new era in New York that views not-for-profit organizations with a far more critical eye, even bordering on outright hostility. While several legislative proposals that might be viewed as hostile to not-for-profit governance of health care were not actually enacted, one will be implemented via an Executive Order and others are likely to be revisited by the Legislature, particularly where the proposals were advanced by the Cuomo Administration.

It didn’t happen overnight. Over the past decades, the dominance enjoyed by the not-for-profit sector in health and human services has been slowly diminished, as for-profit publicly traded health maintenance organizations, home health agencies and, more recently, dialysis facilities have been permitted to operate in the State. The State’s largest not-for-profit health plans now face intense competition from large publicly traded health plans, which led the State’s largest Blue Cross-Blue Shield plan to convert to a publicly traded entity and has encouraged several other non-profit plans to contemplate doing the same.

The latest threats to the not-for-profit health and human services sec-



tor were, at least to some extent, self-inflicted. A series of revelations during the summer of 2011 and in subsequent months over questionable salaries and benefits received by executives in state-supported not-for-profit entities prompted state officials to take a closer look at the voluntary sector in New York. Responding to these media exposés, Governor Cuomo convened a New York State Task Force on Not-for-Profit Entities, which requested detailed compensation and other financial and governance information from not-for-profit organizations throughout New York State. While the Task Force has not, as of this writing, published its findings, its work apparently resulted in the proposals to limit executive compensation that were advanced in January, 2012.

At the same time, the Brooklyn Work Group of the Medicaid Redesign Team viewed the governance of the not-for-profit hospitals in Brooklyn as part of the problem, not part of the solution:

The boards of some of these hospitals have failed to satisfy fully their responsibilities to the organizations and their communities. They have not evaluated financial and clinical performance, set strategic goals to address them, and held management accountable for achieving them. Instead, they have adopted a strategy that seeks

merely to be the last man standing in their communities. It is clear that this strategy is a failed one.

*At the Brink of Transformation: Restructuring the Healthcare Delivery System in Brooklyn*, Report of the Brooklyn Redesign Health Systems Work Group, November, 2011, p. 6.

The Work Group also recommended exploring whether New York might consider lifting the longtime ban on investment by publicly traded for-profit entities in hospitals and nursing homes “to encourage private investment in Brooklyn’s hospitals”—while recognizing that any “such investments should be allowed only under a governance and regulatory structure that would assure accountability for quality, community involvement in governance, and an enforceable commitment to addressing community needs.” *Id.* at 51.

The concerns over executive compensation and the failings and/or limitations of not-for-profit governance resulted in proposals advanced by the Governor and the Legislature during the 2012 budget negotiations—and have been incorporated in an Executive Order that may have a profound impact on executive compensation and administrative expenses within entities that contract with the State of New York. The legislative and regulatory actions proposed and/or taken during early 2012 are summarized below.

**Executive Compensation/Administrative Costs:** The 2012-13 Executive Budget contained a legislative proposal that would authorize a



broad array of state agencies to limit the extent to which state funds may be used to support administrative services, rather than direct care or services, and to preclude state reimbursement for executive salaries in excess of \$199,000 per year. Within a day after the budget proposal was submitted, the Governor issued an Executive Order (Executive Order No. 38, filed with the Secretary of State's office on January 18, 2012), which was essentially identical in its limitations on executive compensation and administrative expense.

The statutory proposal to limit executive compensation and administrative costs was not enacted as part of the 2012-13 State Budget—nor, however, did the Legislature enact a proposal advanced by the State Senate that proposed an alternative approach that would have relied upon the existing IRS compensation guidelines and would have explicitly preempted Executive Order No. 38. As a result, unless subsequent legislation is enacted to substitute for the Executive Order or litigation is commenced to challenge its legal validity, the Executive Order will be implemented and may have significant impacts on entities that contract with the State.

#### ***The Terms of the Executive Order:***

The Executive Order addresses both executive compensation and limits on administrative expenses and can be summarized as follows:

- ***Cap on Executive Compensation:*** The legislation would also provide that state reimbursement would not be provided for “compensation paid or given to any executive by such provider in an amount greater than \$199,000 per annum.” The \$199,000 cap on state-supported compensation could be adjusted annually by state agencies, but may not exceed “Level I of the federal government’s Rates of Basic Pay for the Executive Schedule promulgated by the United States Office of Personnel Management,” which is currently \$199,700. A

contracting entity may seek a waiver from compliance with this requirement from the state agency and DOB or face the termination or non-renewal of the contract.

- ***Cap on “Administration” Expenses:*** At least seventy-five percent of the “state financial assistance or state-authorized payments” for operating expenses of contracting entities must be “directed to provide direct care or services rather than to support the costs of administration”—terms that would be defined by the relevant state agencies. The mandated “direct services” percentage would increase by five percent per year until, no later than April 1, 2015, it reaches eighty-five percent, where it would remain thereafter.
- ***Implementation of the Executive Order:*** The Executive Order anticipated the need for regulations to help clarify its terms, to address unique circumstances and to define a number of the terms left undefined in the Order itself. Although the regulations have not, as of this writing, been issued, a substantial effort has been devoted to try to ensure that the Executive Order realistically addresses these issues, mindful of the importance of attracting high quality leadership to the organizations that contract with the State and the inherent challenges of defining—let alone reducing—administrative costs.

It is anticipated that the regulations will clarify that the Executive Order applies to both not-for-profit and for-profit entities that contract with the State, but will not apply to contracts that are providing services to the State itself. The regulations will only apply to entities that receive a substantial amount of state funding support: entities would have to receive at least \$500,000 in state funding and

at least forty percent of its total revenue must come from state funding or state authorized payments.

- ***Executive Compensation:*** Compensation will be defined as salary, bonus and other unique perquisites but not standard fringe benefits or retirement benefits. As long as the entity does not depend virtually entirely on state support, the regulations will apparently allow other sources of funding to supplement the cap on compensation if state funding is not contributing to the “excess” compensation. It is further contemplated that contracting entities may seek to justify the executive compensation by providing documentation that the compensation was properly determined (through a compensation-setting process that satisfies applicable IRS guidelines) and can be shown to be within a reasonable range of other salaries in the field, based on credible surveys of comparability. The goal of the regulations will be to focus on “outliers” whose compensation varies by some (as yet unspecified) degree from comparable compensation levels in the specific field. Entities that receive a very high percentage of state funding may face a “hard” salary cap. If an entity receives a very high threshold of state funding (perhaps over ninety percent of total funding), the cap on compensation will be a “hard cap” on executive compensation; i.e., one that cannot be supplemented by non-state funding. That “hard cap” will likely be at a higher compensation level, perhaps in the range of \$500,000.
- ***Administrative Expense Cap:*** Implementing the administrative cap may prove to be more complex. The intention was not to replace existing formulas and reimbursement

screens that already seek to limit “indirect” or administrative expenditures. At the same time, the Administration would like to establish some degree of consistency and uniformity on how administrative expenses might be defined and limited across State government. The Administration has emphasized that every effort would be made to err on the side of categorizing expenses as “direct” expenses, including expenses that promote quality of care.

The draft regulations are expected to be published for public comment on or about April 18, 2012.<sup>1</sup> It is now anticipated that the new regulations will not be implemented or enforced until at least January 1, 2013.

**MRT Governance Reforms:** Implementing recommendations of the MRT’s Brooklyn Health Systems Redesign Work Group, the 2012-13 Executive Budget advanced a series of proposals that would have substantially strengthened the role of DOH in its oversight of the governance of hospitals and other health care facilities. Although the recommendations were prompted by the Work Group’s review of hospital governance in Brooklyn, the Work Group expressly recommended that these recommendations be “deployed, where applicable, to support change not just in Brooklyn and not just for troubled hospitals, but across the state and along the continuum of care, among strong and fragile providers alike.”

Even though the Legislature did *not* include the provisions in the final budget, it is worth reviewing how the Executive branch sought to augment its authority over not-for-profit health entities:

- **Summary Suspension or Limitation of the Operating Certificate.** The proposal would have granted the Commissioner of Health the authority to temporarily suspend or limit an operating certificate of a not-for-profit corporation, without a hearing, if: DOH is commencing

an action to revoke the operating certificate for violations of provisions of Article 28 of the Public Health Law; a member of the corporation’s board of directors has been indicted on felony charges; or if the Attorney General has commenced an action to remove a member of the Board.

- **Revocation of the Operating Certificate.** Existing provisions that authorize the revocation of operating certificates of health care facilities when controlling persons and owners of facilities are convicted of felonies would have been extended to authorize revocation where a member of the board of directors or a member of the limited liability company that operates the licensed entity is convicted of a Class A, B or C felony or any other felony related to the operation of a health care facility, Medicaid fraud or a violation of the Public Officers Law.
- **Appointment of a Temporary Operator.** The Commissioner would have been authorized to appoint a temporary operator of an adult care facility, general hospital or clinic on a temporary basis when a statement of deficiencies has been issued that finds “significant management failures, including but not limited to administrative, operational or clinical deficiencies or financial instability” that “seriously endanger the life, health or safety of residents or patients or jeopardize existing or continued access to necessary services within the community.”
- **DOH Review of Changes in the Board of Directors.** Perhaps most dramatic, a proposal was advanced that would have required that any change in the board of directors of a health care facility board be submitted to the Department of Health at least 120 days prior to its ef-

fective date. The forms for this purpose will require information “as may be reasonably necessary for the department to determine whether it should bar the change in directors.”

Although these proposals were not enacted, they signal a willingness by the Administration to directly insert itself in the governance of not-for-profit entities operating health care facilities—and could be resubmitted to the Legislature for further consideration.

**Private Equity Investments in New York Health Care:** A demonstration project was proposed by the State Senate in its budget proposal that would “develop, evaluate and implement a flexible approach to allowing equity investors to invest in and hold an equity interest as operators of health care facilities.” Demonstration projects would be established to allow for investments by operating and equity investor interests in residential health facilities and would allow the facilities to be operated by limited liability companies, which, contrary to current law, could include corporate entities. The demonstration project would be subject to an evaluation. The proposal was not ultimately included in the State Budget.

**Future of Not-for-Profit Entities in the Health and Human Services Areas:** Whether these initiatives mark a permanent change in New York State’s approach to not-for-profit entities or just a momentary bump in the road in the longstanding relationship of State government toward the charitable sector remains to be seen. But not-for-profit entities should be prepared, at least for the foreseeable future, for far more detailed scrutiny of their governance and decision-making than they have previously encountered. And public policy approaches to the not-for-profit sector should consider the historic role played by charitable organizations in New York State.

Not-for-profit service providers employ more than a million New Yorkers, provide the lion’s share of

health and human services to all New Yorkers, and, in particular, are irreplaceable elements of New York's safety net for our most vulnerable citizens. According to a recent report from the Office of the State Comptroller, New York State has nearly 27,000 registered nonprofits and the State has entered into more than 22,000 active contracts with these organizations to provide critical services to New Yorkers.<sup>2</sup> Over 1.2 million New Yorkers are employed by not-for-profit organizations, representing nearly one in five of private sector employees.<sup>3</sup> Of the top twenty employers in New York State, nine are not-for-profit organizations, four of which number among the State's top ten employers.<sup>4</sup>

The economic contributions made by the not-for-profit sector in New York are only part of the story: without not-for-profit organizations, essential public services—educa-

tion, health care, and a broad array of other services for disabled, disadvantaged and aging New Yorkers—would either not be provided at all or would be provided by the public sector at substantially greater cost to the taxpayer. Generally speaking, when these services are delivered by the public sector, the overall costs of administration, overhead, salaries and benefits are higher, not lower, than when delivered by not-for-profit organizations. The mission-driven not-for-profit sector has also long been credited, moreover, with providing these services at a level of quality that at least equals, and often exceeds, that of the public sector.

In sum, given the role that not-for-profit entities play in New York, it is essential that proposals that might negatively impact on the not-for-profit sector be viewed with caution—and that not-for-profit providers of services prepare themselves for what may

be a more challenging environment in the years ahead.

## Endnotes

1. As this edition was about to go to print, the Department of Health issued its proposed rules on executive compensation. See <http://www.dos.state.ny.us/info/register/2012/may30/toc.html>.
2. Office of the New York State Comptroller, "New York State's Not-for-Profit Sector: Delayed State Contracts and Late Payments Hurt Service Providers," November, 2011.
3. L. Salamon, et al., "Holding the Fort: Nonprofit Employment During a Decade of Turmoil," Johns Hopkins University Center for Civil Society Studies, January, 2012, pp. 3, 5.
4. Center for Governmental Research, "Economic Impact of the University of Rochester and its Affiliates," April, 2010, p. 13.

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# The NYSBA Family Health Care Decisions Act Information Center

**The NYSBA Health Law Section has a web-based resource center designed to help New Yorkers understand and implement the Family Health Care Decisions Act—the law that allows family members to make critical health care and end-of-life decisions for patients who are unable to make their wishes known.**

[www.nysba.org/fhcda](http://www.nysba.org/fhcda)



# In the New York State Agencies

By Francis J. Serbaroli

## Observation Unit Operating Standards

Notice of Adoption. The Department of Health amended section 405.19 of Title 10 NYCRR to provide operating standards for observation units. Filing date: December 27, 2011. Effective date: January 11, 2012. *See* N.Y. Register January 11, 2012.

## Home Care Services Worker Registry

Notice of Proposed Rulemaking. The Department of Health proposed adding Part 403; and amending sections 700.2, 763.13 and 766.11 of Title 10 NYCRR; and amending sections 505.14 and 505.23 of Title 18 NYCRR to provide guidance for workers, providers etc. regarding the rights, duties and responsibilities for the Home Care Services Worker Registry. *See* N.Y. Register January 11, 2012.

## Municipal Public Health Services Plan—Radioactive Material and Radiation Equipment

Notice of Emergency Rulemaking. The Department of Health amended Part 40 of Title 10 NYCRR to establish funding for certified counties to inspect radiation equipment and the NYCDOHMH to conduct licensing and inspections. Filing date: December 28, 2011. Effective date: December 28, 2011. *See* N.Y. Register January 18, 2012.

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

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPAP services. Filing date: December 30, 2011. Effective date: December 30, 2011. *See* N.Y. Register January 18, 2012.



## Audits of Institutional Cost Reports (ICR)

Notice of Emergency Rulemaking. The Department of Health amended

Subpart 86-1 of Title 10 NYCRR to impose a fee schedule on general hospitals related to the filing of ICRs sufficient to cover the costs of auditing the ICRs. Filing date: December 30, 2011. Effective date: December 30, 2011. *See* N.Y. Register January 18, 2012.

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

Notice of Adoption. 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 29, 2011. Effective date: January 18, 2012. *See* N.Y. Register January 18, 2012.

## Rates of Reimbursement—Hospitals Licensed by the Office of Mental Health

Notice of Adoption. The Office of Mental Health amended Part 577 of Title 14 NYCRR to freeze rates of payments to freestanding psychiatric centers licensed under Mental Hygiene Law article 31 effective 1/1/12. Filing date: January 3, 2012. Effective date: January 18, 2012. *See* N.Y. Register January 18, 2012.

## Requirements Pertaining to the Investigation and Review of Serious Reportable Incidents and Abuse Allegations

Notice of Adoption. The Office for People With Development Disabilities amended section 624.5(c)(1)(iii) of Title 14 NYCRR to clarify the effective date of recently promulgated regulations. Filing date: January 3, 2012. Ef-

fective date: January 18, 2012. *See* N.Y. Register January 18, 2012.

## Methodology to Determine the Allowable Costs of Continuing Lease Arrangements

Notice of Adoption. The Office for People With Development Disabilities amended section 635-6.3 and Subpart 635-99 of Title 14 NYCRR to modify the method of determining allowable costs of continuing lease arrangements. Filing date: January 10, 2012. Effective date: January 25, 2012. *See* N.Y. Register January 25, 2012.

## Potentially Preventable Negative Outcomes

Notice of Adoption. The Department of Health amended section 86-1.42 to Title 10 NYCRR to deny additional reimbursement for hospital-acquired conditions. Filing date: January 17, 2012. Effective date: February 1, 2012. *See* N.Y. Register February 1, 2012.

## Episodic Pricing for Certified Home Health Agencies (CHHA)

Notice of Proposed Rulemaking. The Department of Health proposed to add section 86-1.44 to Title 10 NYCRR to control over-utilization of CHHA services and more appropriately align payment with services. *See* N.Y. Register February 1, 2012.

## Authority to Collect Pharmacy Acquisition Cost

Notice of Emergency Rulemaking. The Department of Health amended 505.3 of Title 18 NYCRR to establish a requirement that each enrolled pharmacy report actual acquisition cost of a prescription drug to the Department. Filing date: January 25, 2012. Effective date: January 25, 2012. *See* N.Y. Register February 15, 2012.

## Qualified Health Information Technology Entities

Notice of Adoption. The Department of Health amended section 504.9 of Title 18 NYCRR to broaden the definition of a Service Bureau to include

Qualified Entities. Filing date: January 27, 2012. February 15, 2012. *See* N.Y. Register February 15, 2012.

### **Hospital Quality Contribution**

Notice of Adoption. The Department of Health amended Subpart 86-1 of Title 10 NYCRR to collect thirty million dollars annually for the Medical Indemnity Fund. Filing date: January 27, 2012. Effective date: February 15, 2012. *See* N.Y. Register February 15, 2012.

### **Managed Care Organizations (MCOs)**

Notice of Adoption. The Department of Health amended section 98-1.11 of Title 10 NYCRR to specify approval standards for asset transfers or loans proposed by MCOs. Filing date: January 27, 2012. Effective date: February 15, 2012. *See* N.Y. Register February 15, 2012.

### **Repeal of 14 NYCRR Parts 1010, 1020, 1035, 1060 and 1061**

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Parts 1010, 1020, 1035, 1060 and 1061 of Title 14 NYCRR to remove obsolete regulations that are no longer applicable to OASAS certified programs. Filing date: February 7, 2012. Effective date: February 22, 2012. *See* N.Y. Register February 22, 2012.

### **Chemical Dependence Programs for Youth; Additional Locations Operated by OASAS Certified Providers**

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 820 and amended section 810.13(c)(2) of Title 14 NYCRR to repeal an obsolete rule and amend a regulation to conform provisions to a more recently promulgated regulation. Filing date: February 6, 2012. Effective date: February 22, 2012. *See* N.Y. Register February 22, 2012.

### **Repeal of 14 NYCRR Parts 303, 306, 340, 342, 366, 369, 372, 374, 380 and 381**

Notice of Adoption. The Office of Alcoholism and Substance Abuse

Services repealed 14 NYCRR Parts 303, 306, 340, 342, 366, 369, 372, 374, 380 and 381 to remove obsolete regulations that are no longer applicable to OASAS-certified programs. Filing date: February 6, 2012. Effective date: February 22, 2012. *See* N.Y. Register February 22, 2012.

### **Accreditation of General Hospitals and Diagnostic and Treatment Centers**

Notice of Adoption. The Department of Health amended sections 405.1, 700.2, 720.1 and 755.2; renumbering of sections 751.11 to 751.12; and addition of new section 751.11 to Title 10 NYCRR to update accreditation provisions for general hospitals and diagnostic and treatment centers. Filing date: February 3, 2012. February 22, 2012. *See* N.Y. Register February 22, 2012.

### **Reduction to Statewide Base Price**

Notice of Adoption. The Department of Health amended section 86-1.16 of Title 10 NYCRR to impose a reduction to the statewide base price as an interim measure. Filing date: February 3, 2012. Effective date: February 22, 2012. *See* N.Y. Register February 22, 2012.

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

Notice of Adoption. The Department of Health amended Part 63 of Title 10 NYCRR to increase HIV testing and to promote HIV positive persons entering into treatment. Filing date: February 6, 2012. February 22, 2012. *See* N.Y. Register February 22, 2012.

### **Minimum Standards for the New York State Partnership for Long-Term Care Program**

Notice of Proposed Rulemaking. The Department of Financial Services proposed to amend Part 39 (Regulation 144) of Title 11 NYCRR to amend minimum standards for inflation protection, to add a new plan and add disclosure requirements relating to reciprocity. *See* N.Y. Register February 29, 2012.

### **Temporary Rate Adjustment (TRA)—Residential Health Care Facilities (RHCF) (Nursing Homes)**

Notice of Emergency Rulemaking. The Department of Health amended added section 86-2.39 to Title 10 NYCRR to provide a TRA to eligible RHCFs subject to or impacted by closure, merger, acquisition, consolidation, or restructuring. Filing date: February 13, 2012. Effective date: February 13, 2012. *See* N.Y. Register February 29, 2012.

### **Hospital Temporary Rate Adjustments**

Notice of Emergency Rulemaking. The Department of Health amended 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: February 13, 2012. Effective date: February 13, 2012. *See* N.Y. Register February 29, 2012.

### **Temporary Rate Adjustment (TRA)—Licensed Ambulatory Care Facilities (LACF)**

Notice of Emergency Rulemaking. The Department of Health added section 86-8.15 to Title 10 NYCRR to expand TRA to include Article 28 LACFs subject to or affected by closure, merger, acquisition, consolidation, or restructuring. Filing date: February 13, 2012. Effective date: February 13, 2012. *See* N.Y. Register February 29, 2012.

### **Adverse Event Reporting Via NYPORTS System**

Notice of Proposed Rulemaking. The Department of Health proposed to amend sections 405.8 and 751.10 of Title 10 NYCRR to update current provisions to conform with current practice. *See* N.Y. Register February 29, 2012.

### **Amendment to Limitations of Operating Certificates**

Notice of Adoption. The Department of Health amended section 401.2 of Title 10 NYCRR to allow Public Health Law Article 28 facilities to operate at sites not designated on their operating certificate during an emer-



gency. Filing date: February 21, 2012. Effective date: March 7, 2012. *See* N.Y. Register March 7, 2012.

### **Medicaid Managed Care Programs**

**Notice of Emergency Rulemaking.** The Department of Health repealed subparts 360-10, 360-11 and sections 300.12, 360-6.7; and added new Subpart 360-10 to Title 18 NYCRR to repeal old and outdated regulations and to consolidate all managed care regulations to make them consistent with statute. Filing date: February 24, 2012. Effective date: February 24, 2012. *See* N.Y. Register March 14, 2012.

### **October 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. Filing date: February 28, 2012. Effective date: March 14, 2012. *See* N.Y. Register March 14, 2012.

### **Clinic Treatment Programs**

**Notice of Adoption.** The Office of Mental Health amended Part 599 of Title 14 NYCRR to amend and clarify existing regulation and enable providers to seek reimbursement for certain services using State-only dollars. Filing date: February 27, 2012. Effective date: March 14, 2012. *See* N.Y. Register March 14, 2012.

### **Provisions for Medical Director Coverage in Article 16 Clinics**

**Notice of Adoption.** The Office for People With Developmental Disabilities amended section 679.3 of Title 14 NYCRR to scale medical director coverage to the size of the clinic. Filing date: February 28, 2012. Effective date: March 14, 2012. *See* N.Y. Register March 14, 2012.

### **Limitation of New Enrollment to the Healthy NY High Deductible Plan Pursuant to Section 4326(g) of the Insurance Law**

**Notice of Emergency Rulemaking.** The Department of Financial Services added section 362-2.9 (Regulation

171) to Title 11 NYCRR to mitigate large premium increases for current enrollees in Healthy NY by limiting new enrollees to the high deductible plan. Filing date: March 5, 2012. Effective date: March 5, 2012. *See* N.Y. Register March 21, 2012.

### **Visitation and Inspection of Facilities**

**Notice of Adoption.** The Office of Mental Health added Part 553 to Title 14 NYCRR to create a new Part which reflects the agency's expectations regarding visitation and inspection of facilities. Filing date: March 6, 2012. Effective date: March 21, 2012. *See* N.Y. Register March 21, 2012.

### **IRA and Community Residence Reimbursement Methodology**

**Notice of Adoption.** The Office for People with Developmental Disabilities amended section 671.7 of Title 14 NYCRR to update rent allowance offsets based on Supplemental Security Income (SSI) levels for 2012. Filing date: March 6, 2012. Effective date: March 21, 2012. *See* N.Y. Register March 21, 2012.

### **Behavioral Health Organizations**

**Notice of Adoption.** The Office of Alcoholism and Substance Abuse Services added Part 801 to Title 14 NYCRR to ensure compliance by OASAS-certified providers regarding their obligations in relation to Behavioral Health Organizations. Filing date: March 12, 2012. Effective date: March 28, 2012. *See* N.Y. Register March 28, 2012.

### **Unauthorized Providers of Health Services**

**Notice of Emergency Rulemaking.** The Department of Financial Services added Subpart 65-5 (Regulation 68-E) to Title 11 NYCRR to promulgate standards and procedures for investigating and suspending or removing the authorization for health service providers. Filing date: March 9, 2012. Effective date: March 9, 2012. *See* N.Y. Register March 28, 2012.

### **NYS Medical Indemnity Fund**

**Notice of Emergency Rulemaking.** The Department of Health amended

Part 69 of Title 10 NYCRR to provide the structure within which the NYS Medical Indemnity Fund will operate. Filing date: March 13, 2012. Effective date: March 13, 2012. *See* N.Y. Register March 28, 2012.

### **Medicaid Benefit Limits for Enteral Formula, Prescription Footwear, and Compression Stockings**

**Notice of Adoption.** The Department of Health amended Parts 505 and 513 of Title 18 NYCRR to impose benefit limitations on Medicaid coverage of enteral formula, prescription footwear, and compression stockings. Filing date: March 13, 2012. Effective date: March 28, 2012. *See* N.Y. Register March 28, 2012.

### **Behavioral Health Organization Implementation**

**Notice of Adoption.** The Office of Mental Health amended Parts 580, 582 and 587 of Title 14 NYCRR to inform providers of their responsibilities and requirements associated with Behavioral Health Organization implementation. Filing date: March 12, 2012. Effective date: March 28, 2012. *See* N.Y. Register March 28, 2012.

### **Prior Approval Review (PAR) for Quality and Appropriateness**

**Notice of Proposed Rulemaking.** The Office of Mental Health proposed amending Part 551 of Title 14 NYCRR to add provisions for electronic submission of PAR applications. Filing date: March 12, 2012. *See* N.Y. Register March 28, 2012.

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

# New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions  
Compiled by Eugene M. Laks

***Susquehanna Nursing & Rehabilitation Center (DOH administrative hearing decision dated October 14, 2011, David A. Lenihan, Administrative Law Judge).*** The ALJ sustained the reclassification of housekeeping equipment from the nursing home reimbursable capital costs as a rental to facility operating costs. The facility hired an outside housekeeping company and paid the company a separate monthly fee for rental of housekeeping equipment. The facility did not produce a rental contract and failed to establish that it had the possession, use and enjoyment of the equipment. The fee, therefore, did not qualify as a capital cost.

A recalculation of the adult day care facility square footage trace-back percentage was sustained, as the facility failed to establish and provide documentation of alternative uses of the area for nursing home purposes when the adult day care program was not in operation. Reversal by the OMIG of an error in the rate calculation process where fee-for-service clinical laboratory and radiology services costs had been improperly included in the rate also was sustained by the ALJ. However, the OMIG exclusion of in-room TV cable/satellite costs was reversed in this case, considering the rural location of the facility and the patients' best interest.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

***Excellus BlueCross BlueShield Agrees to Refund Payments to Providers and Plan Members Whose Claims for Childhood Lead Screening***



***Were Unlawfully Denied—March 15, 2012—***Responding to a complaint lodged through the Health Care Bureau Helpline, the Health Care

Bureau launched an investigation into complaints of unlawful denials of mandated insurance. Insurance carriers are required to cover lead screening for children under two years old to promote early detection. Excellus BlueCross BlueShield denied hundreds of these blood tests and when members complained to Excellus about the practice, Excellus continued to deny the claims. After the denials, the physician practices either billed the members directly or absorbed the loss themselves. In connection with this investigation, Excellus agreed to refund payments from 2005 through the present and establish a framework for compliance.

***Executive in Non-Profit Organization Arraigned for Embezzlement of \$75,000 from the Empire State Development Corporation and the Office of Children and Family Services—March 13, 2012—***The Public Integrity Unit charged the fiscal officer of Christian Community Benevolent Association ("CCBA") with embezzlement for co-signing \$75,000 from CCBA's accounts to himself with false memo lines. The money came from accounts that were partially funded by member item grants administered by the Empire State Development Corporation and the Office of Children and Family Services.

***Pharmaceutical Company's Marketing Claim That Drugs Were "Medicaid Reimbursable" Leads***

***to Charges and Settlement of False Claims Act Violations—March 1, 2012—***MFCU alleged that KV Pharmaceutical (formerly Ethex Corporation) knowingly caused false claims to be submitted to the Medicaid Program when it actively promoted drugs that were deemed "less than effective" by the FDA. MFCU also alleged that KV specifically claimed that the drugs were "Medicaid Reimbursable." Neither of the drugs is currently on the market and KV entered into a multistate settlement worth \$17 million.

***Misclassification of Drugs Leads to an \$11 Million Multistate Settlement Against Pharmaceutical Company—March 1, 2012—***The Medicaid Prescription Drug Rebate Program sets the amount of a rebate owed to pharmaceutical companies, in part based on whether a drug is an "innovator" drug or a "non-innovator" drug. MFCU charged that Dava Pharmaceuticals classified certain "innovator" drugs as "non-innovator" drugs to reduce its rebate obligations that it would otherwise owe the State.

***Bronx Resident Sentenced to 4-8 Years for Forgery in Medicaid Prescription Drug Scheme—February 16, 2012—***In a scheme with many co-conspirators, Suzanne Benizio forged 250 prescriptions for drugs including OxyContin and Roxicodone. She wrote the scripts out to actual Medicaid patients, obtained genuine Medicaid cards, and then arranged for the prescriptions to be filled at pharmacies across New York State. Ms. Benizio was sentenced to 4-8 years. The Attorney General stated that the proposed "I-Stop" legislation would prevent such a scheme in the future because the bill would require pharmacists to ensure that a prescription for certain medications is

medically necessary and was actually prescribed to the patient.

**Stark Law Whistleblower Case Nets Plastic Surgeon More Than \$500,000—January 25, 2012**—A plastic surgeon highlighted two questionable recruitment agreements with Cayuga Medical Center that violated the Stark Act. The Hospital disclosed that certain agreements it had with physicians did not comply with the Stark Law and agreed to a settlement worth over \$3 million.

**Health Insurers Required to Publish Accurate Provider Directories—January 19, 2012**—Upon receipt of consumer complaints through its Health Care Bureau Helpline, the Health Care Bureau launched an investigation into the accuracy of health insurers' provider directories. The investigation confirmed that many New York insurers failed to keep their participating physician directories accurate and current, resulting in increased costs and delays to patients. For example, the inaccurate directories caused patients to consult with out-of-network doctors whom they mistakenly thought were in-network providers. The patient would then have to pay for the visit out-of-pocket and likely wait to see an in-network physician to continue treatment. Nine health insurers entered into settlements with the State where they agreed to correct listing errors, implement compliance plans to keep the directories current, and refund consumers for amounts paid for services rendered by non-participating providers who were listed in the online provider directory at the time they received services.

**Dental Center Pays Restitution for Claims of Excess Billings for Dental Services—January 9, 2012**—MFCU found that a Lackawanna Dental Clinic billed Medicaid for excess services. Despite Medicaid regulations that permit reimbursement

only for teeth cleanings performed every six months, some Medicaid patients of this clinic received cleanings every three to four months. The clinic also billed separately for cleanings, x-rays, and dental exams when the regulations require these procedures be completed in one visit. The clinic agreed to pay \$325,000 in restitution to the State.

**New York State Office of the Medicaid Inspector General Update**  
Compiled by Marie A. Butchello

**District Attorney Vance Announces Sentencing in Fraud Conviction: Defendant Billed Medical Assistance Program for Prescription Drugs That Were Never Dispensed—March 6, 2012**—A Manhattan pharmacist was sentenced to 6 1/2 to 13 years in state prison for defrauding Medicaid. Following an undercover investigation, it was discovered that the pharmacist purchased prescriptions from Medicaid clients for cash and then billed Medicaid as if the prescriptions were filled and dispensed. OMIG estimates the cost of this fraud at more than \$1.8 million.

**The New York State Department of Health Has Now Posted Administrative Law Judge Decisions on Its Website.** The decisions can be accessed through the following link: [http://www.health.ny.gov/health\\_care/medicaid/decisions/](http://www.health.ny.gov/health_care/medicaid/decisions/).

**A Trio of Brooklyn Pharmacists Must Reimburse State \$393,000 for False Medicaid Bills—March 3, 2012**—Three Brooklyn pharmacists must repay Medicaid nearly \$400,000 following an OMIG investigation finding that the pharmacists billed for drugs that were either not purchased at all or were bought off the street and dispensed. A disparity between the drugs purchased from wholesalers and the amount of drugs billed led investigators to discover the false

bills. The pharmacists also face possible prosecution for Medicaid fraud.

**Compliance Alert 2011-08, regarding the Home Health Provider Self-Assessment Pre-Claim Review Process—December 21, 2011**—Summarizes providers' obligations under Social Services Law § 363-a to utilize a verification organization to review claims prior to submission, provides a link to a list of verification organizations and provides a self-assessment tool that allows providers to evaluate compliance with SSL § 363-a.

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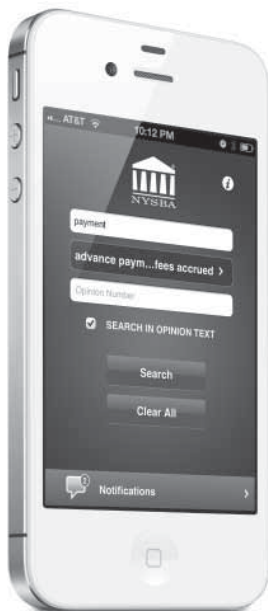
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# For Your Information

By Claudia O. Torrey

## Items of interest:

- On March 13, 2012 Mr. Leon Rodriguez, Director of the United States Department of Health and Human Services' ("HHS") Office of Civil Rights ("OCR"), announced that Blue Cross Blue Shield of Tennessee ("BCBST") agreed to pay HHS \$1,500,000 concerning violations of both the Privacy Rule and the Security Rule of the Health Insurance Portability and Accountability Act ("HIPAA") of 1996. It appears this is the first enforcement action under the Breach Notification Rule ("BNR") of the *Health Information Technology for Economic & Clinical Health Act* ("HITECH"). The BNR requires covered entities to report an impermissible disclosure or use of protected health information ("PHI") to HHS and the media when the breach involves 500 or more individuals. Thus, BCBST reported stolen 57 **unencrypted computer hard drives** containing the PHI of over one million people (names, social security numbers, diagnosis codes, date[s] of birth, etc.); the hard

drives were located in a leased Tennessee facility.

According to Director Rodriguez, the "settlement sends an important message that OCR expects health plans and health care providers to have in place a carefully designed, delivered, and monitored HIPAA compliance program; the HITECH BNR is an important tool and OCR will continue to vigorously protect patients' right to private and secure health information." The BCBST agreement can be viewed at [http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/resolution\\_agreement\\_and\\_cap.pdf](http://www.hhs.gov/ocr/privacy/hipaa/enforcement/examples/resolution_agreement_and_cap.pdf).

- 42 Code of Federal Regulations Part 495 is entitled *Electronic Health Record Technology Incentive Program*, and enables hospitals and other health care professionals to qualify for Medicare and Medicaid incentive payments upon adoption and use of certified electronic health record ("EHR") technology in a "meaningful way." The meaningful use ("MU") incentives have three stages for providers adopting EHRs. In

an announcement on proposed rule on February 24, 2012 ([http://www.cms.gov/apps/media/fact\\_sheets.asp](http://www.cms.gov/apps/media/fact_sheets.asp)) the Center for Medicare and Medicaid Services ("CMS") and the Office of the National Coordinator for Health Information Technology ("ONC") extended Stage One (the MU is the transfer of data to EHRs and being able to share information), allowing providers to attest to Stage Two in 2014 instead of 2013. Stage Two MU consists of online patient access to their health information and ease of electronic health information exchange between providers; under the proposed rule Stage Two is to be implemented in 2014. The proposed rule also gives criteria for EHR technology certification so that the adopted systems are capable of performing the required functions to demonstrate either stage of MU that would be in effect in 2014.

**Claudia O. Torrey, Esq. is a  
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## Special Edition: Public Health Law and Public Health Ethics

By Mary Beth Morrissey and Bruce Jennings, Special Edition Editors

### Introduction

This special issue of the *New York State Bar Association Health Law Journal* is devoted to public health law and public health ethics. The focus for this Spring 2012 issue arose in the context of developing an action plan to promote diversity in the Health Law Section. There is a heightened awareness among Section members of the demands and responsibilities placed upon practitioners in the field of health law, who are increasingly called upon to understand complex issues involving public health—how to assess unmet needs at the population level, how to influence policy and regulation, how to analyze data and conduct research, and how to work collaboratively with professionals in other disciplines. Articles in this collection specifically address policy issues, the needs of special populations; health disparities research, data collection and analysis; and electronic health records. The goal of this issue is to foster dialogue on these important issues, and on the ethical implications of decisions involving health on a population level and efforts to promote healthy individuals in healthy communities.

In the opening article of this special issue, Dr. Guthrie Birkhead, chief public health physician for the New York State Department of Health, provides a description of multisectoral essential public health functions and services. Dr. Birkhead identifies critical public health domains including prevention, assessment of health status through data collection, changing the environment and social determinants of health, addressing health disparities, and workforce development. He also reminds us that attorneys can play important roles in these areas of policy and planning as well as in enforcing laws and assuring safety.

In the section on policy issues, Kathleen Dachille's article on tobacco regulation and Lois Uttley and colleagues' article on mergers involving Catholic and nonsectarian hospitals both provide excellent examples of the role of the legal system and public health advocates in influencing policy outcomes. Each of these articles highlights the importance of local advocacy, collaborations and decision processes in shaping public health policy. Policy challenges in dealing with the obesity epidemic are the focus of Michael Hernández's contribution, in which he too describes the central role of local agencies and groups including the Public Health Association of New York City and the New York City Department of Health and Mental Hygiene. Mary Beth Morrissey, Dana Lustbader and David Leven explain why chronic and serious illness are public health issues calling for palliative approaches to care and pain management, helping to make the links between the role of

public health law, workforce development, prevention, and better health, health care and reduced costs.

Special populations are the subject of articles by Colleen Jackson and Autumn Hurst on innovative approaches to housing and homelessness, and by Morrissey and Tina Maschi on the crisis of health care facing aging inmates in the U.S. prison system. In both of these contributions, there is a well-developed focus on interdisciplinary collaboration in improving public health and in developing public health solutions to social problems.

The section on research, data collection and analysis, and electronic health records opens with a review by Karen L. Illuzzi Gallinari, Julia Goings-Perrot and Brian Currie of important developments in these areas. They explain distinctions between public health law practice and research. Turning to implementation, Patricia Bomba and Katie Orem share information about a developing electronic health records system called e-MOLST, and how it may be used most effectively to serve patients and advance the goals of public health.

This issue of the *Journal* closes with a special report on pain republished with the permission of the Gerontological Society of America. The report summarizes the recommendations made by the Institute of Medicine in its 2011 ground-breaking blueprint for *Relieving Pain in America*, and identifies gaps for future research.

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**We gratefully acknowledge the support of Robert Swidler, Editor, the New York State Bar Association Health Law Section and Diversity Committee members, and all of the contributing authors in putting together this special issue and focus on public health.**

# Overview: Assuring the Public's Health: What Is "Public Health" and What Is the Role of the Law?

By Guthrie S. Birkhead

With the passage of the Patient Protection Affordable Care Act (ACA) in 2009, and its promise of near universal health insurance coverage, one might think that the future health of the public in the U.S. is assured. Indeed, the implementation of the ACA over the next 3 years will result in many more people having health insurance. The new law requires that health insurance covers not only the diagnosis and treatment of illness but also clinical preventive measures such as immunizations and cancer screenings without patient co-pays or deductibles that might impede access. Certainly for the readers of the *Health Law Journal*, the ACA represents a powerful demonstration of society's exercise of the law to improve health, notwithstanding that some of the law's provisions are undergoing legal challenges.

All the attention to the ACA, however, leaves open the question whether it alone, even if fully and successfully implemented, is sufficient to achieve the dramatic improvements in the health of the population that are necessary to bring the overall health status of the U.S. up to the level of other developed and even some developing nations.<sup>1</sup> Does health insurance assure access to health care? Is access to health care alone sufficient to assure good health? What are the most important underlying determinants of health, what are the most effective methods to address them, and whose responsibility is it to do so? The answers to these questions move the discussion of improving health into the realm of "public health," an arena of policy, law and action broader than the health care system itself. It is one where, as outlined in this commentary, many societal sectors and professional disciplines including the legal profession are critical components that must be engaged to make progress. Public health's breadth is well illustrated by the wide variety of topics contained in this issue of the *Journal*.

## Defining Public Health

C.E.A. Winslow, one of the founders of the public health movement, wrote almost a century ago, in a definition that needs no updating, that public health is "the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals."<sup>2</sup> The Institute of Medicine (IOM) in its landmark 1988 report *The Future of Public Health*<sup>3</sup> and an update to that report in 2003<sup>4</sup> lays out the current framework that describes public health as the actions society takes "collectively to assure conditions in which people can be healthy." Both definitions underscore a basic theme of public health: the collective nature of the endeavor. Public health is not solely the domain of governmental health departments, but also of many sectors of society that make up the broader public health system.

Health departments have various necessary roles in this system to collect data, devise policy, enforce laws, and administer funds for public health programs. However, governmental action alone is often not sufficient to address the public's health. Other partners such as community groups, employers, academia, the media, and the medical care system must be involved.<sup>4</sup> Similarly, many different disciplines are needed to address public health, not only physicians and nurses, but also statisticians, epidemiologists, information technology specialists, lawyers, health educators, social workers, and media and marketing professionals, both within and outside of government. The legal profession plays important roles to develop policy, translate it into statutes and regulations, and to enforce them.

**Table 1.**

### Ten Great Public Health Achievements—United States, 1900-1999.

- |   |   |
|---|---|
| 1. Vaccination  | 6. Safer and healthier foods                      |
| 2. Motor vehicle safety                                     | 7. Healthier mothers and babies                   |
| 3. Safer workplaces   | 8. Family planning                                |
| 4. Control of infectious diseases                           | 9. Fluoridation of drinking water                 |
| 5. Decline in deaths from coronary heart disease and stroke | 10. Recognition of tobacco use as a health hazard |

Source: CDC. Ten great public health achievements—United States, 1900-1999. MMWR 1999; 48:241-3.



## Ten Public Health Achievements of the 20th Century

Examining the ten most important public health achievements of the 20th century proposed by the Centers for Disease Control and Prevention (CDC) illustrates how important legal actions are in assuring the public's health (Table 1).<sup>5</sup> For example, childhood vaccinations are responsible for preventing tens of thousands of deaths and billions of dollars over the lifetime of each annual birth cohort. However, vaccines are effective only if used. High levels of population coverage are needed to provide "herd immunity" which can eliminate disease transmission. Legal mandates for vaccinations for children to attend school are the most effective means to attain sufficiently high vaccination levels to achieve herd immunity. They have resulted in the disruption of transmission of diseases like measles, which used to cause thousands of deaths and cases of brain damage a year, in the U.S.

The dramatic decline of infectious diseases from the leading causes of death in 1900 was due in large part to improvements in community sanitation that assured clean public water supplies, effective waste and sewage disposal, and safe food supplies. These were achieved through the application of public health statutes and legal enforcement. Control of infectious diseases like tuberculosis was made possible by the development of antibiotics but required public health actions like mandated reporting of tuberculosis cases and mandated directly observed therapy, with occasional resort to court orders to assure treatment, to achieve the current low levels of disease. Legal measures have also been important in the prevention and control of sexually transmitted diseases and HIV/AIDS. Most recently in New York State, a new statute requires the universal offering of HIV testing during primary care medical visits. This was in response to data that many people with HIV are unaware they are infected. Learning one's HIV status is important not only to promote access to treatment to prevent progression to AIDS but also to reduce transmission of HIV to others.

Other public health achievements show the interdisciplinary nature of public health along with the central role of legal action. Motor vehicles have been made safer by mandating seat belts and seat belt use, air bags and many other requirements. Workplace safety under the federal Occupational Safety and Health Act has prevented thousands of deaths and cases of disability. Child health has been dramatically improved by mandating folic acid supplementation of flour to prevent congenital malformations such as spina bifida, removal of lead from gasoline and testing of newborns for inborn errors of metabolism. Universal newborn testing for phenylketonuria (PKU) has eliminated one of the leading causes of mental retardation. Water fluoridation has resulted dramatically

improved dental health although its full potential has not yet been realized

## The Central Role of Prevention

One hallmark of a public health approach to improving health is a focus on disease prevention. This distinguishes public health from health care, which is often focused on curative medical care. Prevention measures include vaccinations to prevent disease (primary prevention) or cancer screening to permit early detection and successful treatment of disease (secondary prevention). Modifying behaviors like diet and exercise can prevent heart disease, stroke, and cancer, the leading causes of death. Reducing exposure to environmental toxins (cigarette smoke being one of major importance) can prevent these same conditions. Prevention of smoking, an addictive behavior, is more effective than smoking cessation after the fact. Important legal approaches to prevention include high cigarette taxes that reduce smoking initiation by teenagers.

Public health has traditionally been dramatically underfunded compared to curative medicine in part because prevention is hard to sell to policy makers and funders. When prevention is successful, nothing happens, no one becomes ill, there are no headlines; prevention can be invisible. Also, the effects of prevention are often not felt for years. Heart disease takes many years to develop from factors such as poor diet and lack of exercise; cancer takes many years to develop from cigarette smoking. Recently there has been greater emphasis on using business tools like return-on-investment (ROI) analyses in public health to make a better business case for prevention. The Trust for America's Health has estimated that the effective application of evidence-based community prevention strategies such as access to fresh fruits and vegetables in farmers markets, restaurant menu calorie labeling, opening school gymnasium facilities to the public evening and weekends, smoking cessation assistance and increased cigarettes taxes would have a slightly negative ROI in 1-2 years of 0.96:1 but a significant positive ROI of 5.6:1 in 5 years and 6.2:1 in 10-20 years.<sup>6</sup> ROI analysis was probably instrumental in getting clinical preventive services included in the ACA without co-pays or deductibles as well as community preventive such as menu calorie labeling in national chain restaurants. Similarly, the recent NYS Medicaid Redesign Team included some clinical and community preventive services such as coverage for home assessment of lead poisoning hazards and asthma triggers; lactation counseling to promote breastfeeding, expanded tobacco cessation counseling, and diet and exercise prevention counseling for pre-diabetics in its phase 1 and phase 2 recommendations with the expectation of health care savings in the future.<sup>7</sup>

Other elements of a public health approach include changing health behaviors through actions on a community or population level. Many health problems have their origin in unhealthy behaviors. It is estimated that behavioral factors may account for as much as half of premature mortality. The factors of genetics and environmental exposure are estimated to account for roughly 20% each, while access to health care may account for only 10% of premature mortality.<sup>8</sup> Changing human behavior on an individual level is difficult, as anyone knows who has tried to improve their diet, eat less and increase exercise on an ongoing basis. Public health approaches attempt to make changes to the environment in which people live to make healthy behaviors automatic or the default choice. Examples include community designs that encourage walking and bicycle riding, removal of harmful trans fats from foods, and making healthy food choices readily available and affordable even in the poorest neighborhoods. Again, the multi-sectoral nature of public health and the importance of legal remedies are evident. The phrase “health in all policies” has been coined to suggest that the health impacts and potential benefits be considered in policy discussion in many sectors from community zoning requirements to transportation policy to community economic development. The phrase embodies a challenge to everyone working within and outside of public health, including the legal profession, to find innovative ways to consider public health thinking in their work.

A final principle underlying public health approaches is the recognition that socioeconomic factors, the so-called “social determinants of health,” are closely linked with health status. Socioeconomic status, includ-

ing educational attainment, housing status, and income, is a key factor in determining health status. Persons with low socioeconomic status have less ability to pursue a healthy lifestyle, tend to smoke more and to have poorer diets, experience more interpersonal violence, may have less access to preventive health care, and may experience higher levels of stress leading to disease. Actions to improve socioeconomic status can improve health. For example, provision of stable housing to homeless persons has been shown to improve health outcomes for persons with diabetes, HIV/AIDS and other chronic diseases. Improving socioeconomic status is not directly the public health department’s responsibility, but it is a necessary part of what the broader public health system and society must address to improve health.

## The Role of Health Departments: Core Public Health Functions and Essential Services

In its 1988 report, the IOM laid out three core functions to describe the role of governmental public health departments as the coordinators of the broader public health system described above: assessment, policy development and assurance (3). In 1994, a national committee further developed these ideas by describing ten essential public health services (ES) that form a framework for understanding the responsibilities of public health departments (Table 2).<sup>9</sup> The contributions of the legal profession to public health are most prominent in ES5 (develop policies and plans that support individual and community health efforts) and ES6 (enforce laws and regulations that protect health and ensure safety). In addition, the legal profession plays an important role in several other essential services.

**Table 2.**

### The Ten Essential Services Public Health Services.

- |  |   |
|--|---|
| 1. Monitor health status to identify and solve community health problems.            | 6. Enforce laws and regulations that protect health and ensure safety.  |
| 2. Diagnose and investigate health problems and health hazards in the community.     | 7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable. |
| 3. Inform, educate, and empower people about health issues.                          | 8. Assure competent public and personal health care workforce.  |
| 4. Mobilize community partnerships and action to identify and solve health problems. | 9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services.               |
| 5. Develop policies and plans that support individual and community health efforts.  | 10. Research for new insights and innovative solutions to health problems.  |

Source: Public Health Functions Steering Committee, 1994. Available at <http://www.cdc.gov/nphsp/essentialservices.html> (accessed 2/19/12).

Assessment of the health status of the population is one of the oldest legal powers and responsibilities of public health departments. Assessment occurs through data collection (ESs 1 and 2) of birth and death certificates and mandated reporting of identifiable health information of selected communicable diseases, cancers, and other conditions. This reporting is allowed through a public health exception in the Privacy Rule of the Health Insurance Portability and Accountability Act.<sup>10</sup> Such data are held by health departments under strict confidentiality protections. State and local departments also take direct action based on these reports, for example, to detect the source and prevent the spread of communicable diseases. These public health program activities that utilize the data, including program evaluation, usually do not trigger Institutional Review Board (IRB) oversight. They are not considered to be research under the federal Office of Human Research Protection definition as an investigation “designed to develop or contribute to generalizable knowledge” (see <http://www.hhs.gov/ohrp/>). An IRB approval or waiver may be sought if the data are used for purposes not directly related to the conduct of the specific program.

A competent public health workforce, both in health departments and public health system partners, is a key to success (ES 8). For the legal profession, efforts are underway by the Centers for Disease Control and Prevention, the lead federal public health agency, to develop a public health law program (see <http://www2.cdcc.gov/phlp/>). A set of competencies for legal practitioners in public health have been proposed (see [www.publichealthlaw.net](http://www.publichealthlaw.net)).

## Measuring the Health Status of New Yorkers and Determining Public Health Priorities

Determining public health priorities should be based on an examination of the major health problems facing the population. Mortality rates show that heart disease, cancer, chronic lower respiratory disease, stroke and pneumonia were the leading immediate causes of death recorded on death certificates. New York ranked 18th among states in the U.S. in a recent compilation of health statistics which included disease outcomes, health deter-

## What Do You Think NY's Public Health Priorities Should Be?

The State Health Department and the Public Health and Health Planning Council (PHHPC) are seeking public and stakeholder input on priorities for the next 5-year state health improvement plan: *The Prevention Agenda 2012-2017*.

An ad hoc committee of the PHHPC has developed proposed priorities and criteria to serve as a catalyst for comments. The proposed priorities are:

- Prevent Chronic Disease;
- Advance a Healthy Environment;
- Healthy Mothers, Babies and Children;
- Prevent Substance Abuse, Depression and Other Mental Illness, and
- Prevent HIV, STIs and Vaccine Preventable Diseases.

A set of slides with descriptions of the proposed priorities and other information about the project can be found at [www.health.ny.gov/PreventionAgenda2013](http://www.health.ny.gov/PreventionAgenda2013).

The Health Law Section and its members are encouraged to offer their views about these proposed priorities. If you would like to do so, please contact the project staff at [prevention@health.state.ny.us](mailto:prevention@health.state.ny.us). Please do so promptly.

minants and health disparity measures (see <http://americashealthrankings.org/ny>). New York ranks relatively poorly among states in cardiovascular deaths and diabetes. Not measured in that ranking, New York is one of the states most impacted by the HIV/AIDS epidemic.

Looking at risk factors for preventable deaths is another way to suggest prevention priorities. National estimates suggest that almost half of the deaths in 2000 were due to the following underlying causes: tobacco use (18.1%), poor diet and physical inactivity (16.6%), alcohol consumption (3.5%), microbial agents (3.1%), toxic agents (2.3%), motor vehicle crashes (1.8%), firearms (1.2%), sexual behaviors (0.8%), and illicit use of drugs (0.7%).<sup>11</sup> Since 2000, poor diet and physical inactivity have edged closer to tobacco use as the leading underlying cause of death. In addition, drug abuse, including prescription drug abuse, has emerged as a major concern on a par with motor vehicle deaths.

Examining health differences by racial, ethnic and gender groups, so-called “health disparities,” is another approach to focus public health efforts. In New York, Blacks and Hispanics have 4-5 times the rate of teen pregnancy and 9 and 6 times, respectively the prevalence of rate of HIV/AIDS as whites; Hispanic children age 2-4 in the WIC program have a prevalence of obesity 50% higher than whites; Black and Hispanic children under age 17 years have a rate of hospitalization for asthma 6 and 4.5 times higher, respectively, than White children; Black and Hispanic pregnant women are twice as likely to have late



or no prenatal care and experience higher rates of infant mortality; gay and bisexual men have much higher rates of syphilis and HIV infection compared to heterosexual men. Health disparities also may be geographically based. There may be less access to cancer screening services in rural areas. Social determinants of health likely underlie many of these differences and present a challenge to find solutions.

New York is also a major port of entry for travelers and immigrants entering the U.S. With international air travel, unusual infectious and tropical diseases can arrive in the U.S. in only a few hours. In 1999, New York was the site of the first cases of West Nile virus infections likely imported from the Middle East, whether by an infected person, animal or mosquito is not known. In 2009, New York City had the first large outbreak of the H1N1 influenza pandemic strain imported from Mexico. New York has also been the target of both man-made and naturally occurring disasters. This highlights that public health emergency response and preparedness, including legal preparedness to issue and enforce isolation and quarantine orders, are important functions for state and local health departments.

A set of current New York public health priorities for the period 2008-2012 are found in the "Prevention Agenda Towards the Healthiest State."<sup>12</sup> Ten priority areas for improving health include chronic diseases, healthy environment, maternal child health, infectious diseases, mental health and substance use, physical activity and nutrition, tobacco, injuries, community preparedness and access to health care. For each priority area, the Prevention Agenda website contains specific goals for provision of preventive services and reduction in disease as well as references on evidence-based interventions and list of partner organizations. Each county health department was asked to engage local partners in developing their community health assessment and municipal health service plans required under Article 6 of the NYS Public Health Law. Hospitals have a similar requirement to produce Community Service Plans every three years. A planning effort is now under way to develop the next 5-year plan for the period 2013-2017. Efforts will be made to reach out to many sectors, including the legal sector, to help establish the public health priorities for the next state health improvement plan.

## Challenges and Opportunities in Public Health and the Role of the Law

New and innovative approaches, including legal ones, are needed to tackle the leading health issues affecting the population today. Reduction of smoking has been a major success, but tobacco use remains the leading cause of preventable premature mortality in the

population. Clean indoor air laws, high cigarette taxes, and smoking cessation education have brought smoking rates to their lowest level on record. Additional steps will probably be necessary to make significant additional reductions. The New York State Medicaid Redesign Team is in the process of greatly expanding Medicaid coverage for smoking cessation counseling.

Obesity and physical inactivity are fueling an epidemic of diabetes and may slow or reverse the downward trend of heart disease and stroke. Can the experience with tobacco control inform the policy and legal approaches to improving diet and physical activity? Some communities are already trying out possible solutions like transfat bans and menu calorie labeling in restaurants, or local zoning ordinances to guide healthy community development, or school food and physical activity policies. Which of these local policy and legal initiatives will be successful and warrant scaling up to state or nationwide adoption only time will tell. This is an opportunity for legal professionals to get involved in their local communities.

Increased attention also needs to be given to addressing the social determinants of health and the obvious health disparities that exist in the population. Incorporating health concerns into discussions of education, housing and job programs may suggest new approaches that will help those efforts yield dual benefits.

Though not mentioned in this paper, significant challenges and opportunities are presented by the movement to develop electronic health records and to link them together. There is an obvious potential to improve the understanding of the population's health and health care by aggregation and analysis of these data, but the confidentiality and security of the data must be maintained.

Finally, the federal government has left to the states the decision about which clinical preventive services to cover without co-pays or deductibles in the health insurance exchange programs under the ACA. An understanding of the value and return on investment of these preventive services should help in assuring that these services are covered.

These are indeed interesting times with many challenges but also with many opportunities. An understanding of public health principles suggests new ways to approach improving health. The law has an important role to play.

## Endnotes

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- Acknowledgements:** The author thanks Sylvia J. Pirani, MPH, MS, Nirav R. Shah, MD, MPH, and Susan F. Birkhead, MPH, RN for reviewing the manuscript and providing insightful comments.
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### ***SAVE THE DATE***

Health Law Section

### ***Fall Meeting***

Friday, October 26, 2012

State Bar Center  
One Elk Street  
Albany, NY 12207  
518-487-5680

### ***TOPIC: NY Health Reform***

10:30 a.m. - 3:30 p.m.

More details, including registration information, will be available closer to the meeting.  
For more information, contact: [lbataille@nysba.org](mailto:lbataille@nysba.org)

# Using Law to Improve Public Health: The Example of Tobacco Regulation

By Kathleen Hoke Dachille

Tobacco use has been the leading cause of preventable death in the United States for decades<sup>1</sup> yet public health advocates have struggled to secure legislation effectively regulating tobacco products and their use. This is largely due to the role tobacco played in the economic development of the United States, particularly in the southern states, and the power tobacco companies wielded with Congress.<sup>2</sup> Although tobacco use has declined significantly in recent decades and our country no longer relies on tobacco crops for economic stability, tobacco products still maintain a prominent place in American culture, often serving as the straw man in debates over how public health regulation threatens the concept of American freedom.<sup>3</sup> Understanding the successes and challenges of the tobacco regulation movement may benefit public health officials and advocates seeking to address other public health issues.

Public health professionals have rallied against tobacco use for many years, employing traditional public health practices. Public health researchers studied the health impacts of smoking and exposure to secondhand smoke, the dynamics of addiction and cessation, the impact of tobacco marketing on prevalence of use in certain segments of the population, and much more. Important research on these issues continues today. Public health practitioners at state and local health departments and philanthropic organizations used this research to design and implement public education campaigns that inform consumers of the dangers of tobacco use and exposure to secondhand smoke, discouraging initiation and encouraging cessation. Moreover, the research aided in the development of drugs and counseling programs used to assist in tobacco cessation. State and local health departments play a critical role in offering cessation drugs and services to smokers. Yet public health officials long ago recognized that public education and health services alone could not resolve the profound negative impact of tobacco use on the public's health. These officials turned to public health policy, primarily in the form of statutes and regulations, to attack the leading cause of preventable death in the United States.

Development of the modern discipline of public health law coincided with the growing need to address tobacco use with more than the traditional tools of public health professionals. To be sure, using laws to protect and preserve the public's health is not a modern or novel concept; boards of health with plenary regulatory power

have been in existence for well over a century.<sup>4</sup> But the drive to reduce the toll of tobacco use through law provides unique and important insight into the role that lawyers and the legal system can play in improving public health.

This article explores some areas of tobacco regulation that demonstrate how law has been used to advance public health; the article is by no means comprehensive as decades of tobacco regulation could not fit neatly into any one article. It is my hope that this discussion will not only serve to reinforce those working in tobacco regulation but that it will also provide inspiration to those working on other areas of public health in which legislation or other policy change may be helpful.

## Local Tobacco Regulation as a Key to Success

History and current experience show that fundamental changes in public health regulation in the United States often start at the local level; this is particularly true with respect to tobacco control.<sup>5</sup> For decades, the tobacco industry exercised tremendous power at the federal level, securing exemptions from many federal statutes, such as the Consumer Product Safety Act, the Fair Packaging and Labeling Act, and the Comprehensive Drug Abuse Prevention and Control Act, among others.<sup>6</sup> Similarly, the industry exerted significant control over state legislatures. "[T]he tobacco lobby prefers to lobby at the state level, rather than the local level where it loses many political battles. Local venues are often better for public health...."<sup>7</sup> For this reason, much of what is now widely accepted as sound public policy in tobacco control developed at the local level.

Clean Indoor Air laws, which prohibit smoking in public places and workplaces, may be the best example of sound tobacco control policy that started at the local level. While today all states have some indoor workplace smoking restrictions and at least 23 states have passed comprehensive Clean Indoor Air laws,<sup>8</sup> in many jurisdictions—including California and Massachusetts—the statewide laws were passed after a majority of local jurisdictions had already passed comprehensive clean indoor air ordinances.<sup>9</sup> At the state level, the restaurant industry, often fueled and funded by the tobacco industry, exerted sufficient power to fend off such laws.<sup>10</sup> At the local level, however, public health advocates were able to secure the protective ordinances. Ultimately, when a significant



portion of the population is covered by a local clean indoor air law, even the restaurant industry stops fighting a statewide law. The local approach to clean indoor air regulation is still working today—in South Carolina there is no statewide law, yet nearly 30 local jurisdictions have passed comprehensive clean indoor air ordinances; the same is true for West Virginia.<sup>11</sup> To preserve this local power, public health officials and their attorneys must be aware of any attempts to preempt local power to regulate indoor smoking. Many of the jurisdictions with weak state laws also face state preemption<sup>12</sup> as the industry is aware that local power is far more likely to be exercised in a comprehensive and effective manner.

Similarly, and likely more helpful to current efforts in other areas of public health, local jurisdictions have passed ordinances restricting tobacco advertising. In 1987, the City of Amherst, Massachusetts, passed an ordinance prohibiting cigarette advertising on public transportation.<sup>13</sup> Perhaps because the Amherst ordinance was not challenged by the tobacco industry in court, in the early 1990s, a handful of other local jurisdictions imposed similar restrictions and others passed ordinances regulating outdoor cigarette advertising in proximity to schools and playgrounds.<sup>14</sup> Again, no legal challenges were filed. The tobacco industry was ultimately provoked into filing litigation in 1994 when the City of Baltimore passed a ban on cigarette (and alcohol) advertising on billboards in residential areas.<sup>15</sup> Ultimately Baltimore City prevailed in the Fourth Circuit Court of Appeals, which found that the City's interest to "protect children who are not yet independently able to assess the value of the message presented" was sufficiently related to the ban on billboard advertising of tobacco products to survive First Amendment scrutiny.<sup>16</sup> Baltimore City's success inspired similar regulations at the local level across the country.<sup>17</sup> All of this local legislative action flourished despite a federal law preempting state and local regulation of cigarette advertising and marketing, the Federal Cigarette Labeling and Advertising Act (FCLAA).<sup>18</sup> Local jurisdictions, supported by aggressive and bright municipal attorneys, carefully crafted their laws to avoid the preemption issue.

It remains true today that the most dynamic and effective tobacco regulation is taking place at the local level, in some respect instigated and supported by federal policy. The Family Smoking Prevention and Tobacco Control Act (FSPTCA),<sup>19</sup> passed by Congress in 2009, gives the Food and Drug Administration (FDA) regulatory power over tobacco products. Interestingly, the Act also repeals most of the state and local preemption language that previously appeared in FCLAA<sup>20</sup> and makes clear that the new provisions are, for the most part, not preemptive of more rigorous state or local regulation. Many public health professionals—and surely public

health lawyers—consider this an important change that will allow local regulation to grow more aggressively than was possible under the stronger FCLAA provisions. Indeed, through American Recovery and Reinvestment Act (ARRA) and Affordable Care Act Public Health Fund Community Transformation grants, state and local jurisdictions have received federal funding to support tobacco regulation efforts. A fair interpretation of this federal action is that even with the FSPTCA and a federal agency responsible for reducing the public health harm from tobacco use, the federal government is looking to state and local jurisdictions to take the lead in novel and aggressive tobacco regulation.

Local jurisdictions have taken on the challenge with verve. While the FSPTCA bans the sale of flavored cigarettes, local jurisdictions have taken the bold step to restrict the sale of flavored non-cigarette tobacco products, such as cigars and smokeless tobacco. New York City's ordinance banning flavored tobacco products recently survived a legal challenge<sup>21</sup> and shortly thereafter the City of Providence, Rhode Island, imposed a comparable restriction (now the subject of litigation).<sup>22</sup> Similarly, FDA regulations under the FSPTCA prohibit the sale of cigarettes in packages of less than 20, and local ordinances have imposed a minimum pack size on cigars. Baltimore City<sup>23</sup> and Prince George's County,<sup>24</sup> Maryland, have imposed a 5-per-pack minimum for cheap cigars popular among youth; the provisions are currently stayed pending legal challenge. Undeterred by the threat of litigation, the Boston Public Health Commission<sup>25</sup> recently imposed a 4-per-pack minimum on cigars and other local jurisdictions around the country are considering such action. Public health professionals working in tobacco regulation are aware that cheap, flavored cigars have become the product of choice for young people. While the FDA slowly determines how to use its vast and complex regulatory power, local jurisdictions are taking action today.

In addition to the packaging and flavored provisions, public health attorneys are currently exploring additional approaches to regulating tobacco advertising and marketing, with an emphasis on what local jurisdictions may lawfully impose. The Tobacco Control Legal Consortium published a series of factsheets after the passage of the FSPTCA detailing state and local action that may be possible under the new law<sup>26</sup> and recently published toolkits that clearly explain how local jurisdictions may regulate tobacco advertising and placement.<sup>27</sup> And New York's Center for Public Health and Tobacco Policy has developed helpful materials on regulation of the tobacco sales environment that may be used by state and local public health officials across the country.<sup>28</sup> Local jurisdictions with the interest and willingness to adopt innovative tobacco regulation have the resources and support of ex-

perienced public health attorneys as they approach these issues.

Lastly, any article explaining how local jurisdictions are leading the charge in tobacco regulation should mention the unique contributions of the City of San Francisco. In 2008, San Francisco passed a law prohibiting the sale of tobacco products at pharmacies on the basis that the health-supporting mission of pharmacies was undermined by the sale of the product contributing to the leading cause of preventable death.<sup>29</sup> Several local jurisdictions in Massachusetts, including Boston and Needham, have passed similar provisions.<sup>30</sup> And in 2009, San Francisco imposed a 20¢ fee on each pack of cigarettes as the cost of clean-up associated with cigarette debris.<sup>31</sup> These are fine examples of the type of novel and impactful regulations we can expect to see from local governments.

### Taxation as Health Policy

One issue that may not be addressed by local governments is tobacco tax increases as a means to reduce tobacco use. Because many states preempt local jurisdictions from imposing taxes, state law is generally the source of health policy through tobacco taxation. In most states, tobacco products are subject to excise taxes in addition to any state sales tax. The federal government imposes a \$1.01 tax per pack of cigarettes.<sup>32</sup> Every state imposes a tax on cigarettes, varying from 17¢ per pack in Missouri to \$4.35 per pack in New York.<sup>33</sup> Most states also tax non-cigarette tobacco products, known as “other tobacco products” or “OTP.” State taxation of OTP varies greatly in that some states impose an ad valorem tax—typically a certain percentage of the wholesale price of the product—and others impose a weight-based tax. Many states impose a cap regardless of which approach is employed.<sup>34</sup> Within OTP, products may be taxed differently as well. For example, in Connecticut, snuff is taxed at \$1.00 per ounce, chewing tobacco at 50% of wholesale price and cigars at 50% of wholesale price with a cap of 50¢ per cigar.<sup>35</sup> Federal taxes on OTP are product-based as well.<sup>36</sup> Some local jurisdictions not preempted by state law impose additional taxes on tobacco products—such as New York City’s \$1.50 per pack tax on cigarettes.<sup>37</sup>

Taxation of cigarettes as health policy started in the 1980s when economists demonstrated that, despite the fact that cigarettes are highly addictive, cigarette price increases would result in reduced demand. In the 30 years since, states have successfully used tax increases as health policy to deter smoking initiation and encourage cessation.<sup>38</sup> Today there is little doubt that raising tobacco taxes decreases tobacco use. Although cigarette taxes have been the focal point of this policy movement, a recent trend shows states seeking to increase the tax on OTP for the same reasons. For example, the Maryland General As-

sembly recently increased the tax on cigars from 15% of wholesale price to 70% of wholesale price.<sup>39</sup> This follows data showing that as cigarette use declined in Maryland, the use of OTP, specifically cheap cigars, increased, particularly among young people.<sup>40</sup>

In addition to reaping the benefits of reduced tobacco use, public health officials have sought or supported tobacco tax increases for the purpose of funding important tobacco control programs, such as public education, enforcement of youth sales prohibitions, counter marketing, and access to cessation resources.<sup>41</sup> This is the ultimate win-win for public health—use of the dangerous product declines at the same time that public health professionals are provided more resources to prevent initiation and assist in cessation. Moreover, increasing the tobacco tax, particularly in support of public health programming, is politically palatable as smokers make up a minority of the population and taxes on non-essential items are generally better received by the public.

Although not all public health issues can be addressed through taxation, there may be products that contribute significantly to public health problems that could be subject to a tax scheme designed to increase price, decrease consumption or use and fund relevant public health programs. For example, a tax on tanning services might eliminate some younger, more price-sensitive consumers and could fund educational efforts related to skin cancer prevention. Those looking at taxation as a potential public health policy ought to examine or develop sound economic studies to determine the potential impact of the tax. As with any health policy, a sound evidence base is necessary. Public health professionals ought to consider requiring those taxes be set aside for programs designed to address the particular public health problem to which the taxed product contributes. That may make an otherwise unpopular tax increase (as if there are any popular tax increases) more politically palatable and hence more likely to pass. More importantly, such an approach ensures funding for critical programming to continue to address the public health problem. There is no reason that tobacco should be unique in using tax policy to address public health problems.

### Legal Issues of Concern in Public Health Generally

A few legal issues that frequently arise in tobacco regulation warrant specific mention here as these issues permeate public health law more broadly as well. As mentioned above, preemption has played a role in preventing state and local tobacco regulation.<sup>42</sup> For decades, FCLAA preempted state and local regulation of cigarette advertising or promotion if that regulation was based on health. Although some local laws survived FCLAA scru-

tiny—such as the Baltimore City billboard ban—many were struck down as preempted. At the same time, states passed laws restricting local jurisdictions from tobacco regulation, specifically related to indoor smoking, enforcement of youth sales restrictions and tobacco advertising. Recognizing the stifling impact of these laws, a goal of the Center for Disease Control's *Health People 2020* initiative is elimination of state preemption of local tobacco regulation. The CDC recently reported that while progress has been made in alleviating preemption of local regulation of indoor smoking, no progress has been made in lifting preemption of local regulation on youth access or tobacco advertising.<sup>43</sup> In states with strong preemption, much of the local regulation touted in the first section of this article is impossible to achieve. In those states, local public health professionals and their lawyers must first seek repeal of preemption before they can embark upon innovative tobacco control policy.

Recognizing the negative impact of preemption on public health policy, the Robert Wood Johnson Foundation funds Preemption Watch to provide technical assistance to public health professionals seeking to secure the repeal or prevent the imposition of preemptive provisions that restrict local public health regulation.<sup>44</sup> Resources available on the Preemption Watch website are easily adapted for use in any jurisdiction and for any issue of public health regulation. Public health attorneys must be adept and vigilant at recognizing the potential preemptive impact of federal and state legislative proposals and advise their local public health officials accordingly.

Public health attorneys must also familiarize themselves with First Amendment jurisprudence to ensure public health legislation is drafted and supported to best survive challenge. As mentioned above, local jurisdictions have been encouraged to consider new restrictions on tobacco advertising in light of the repeal of FCLAA's broad preemption. Public health officials may be looking to similar restrictions with respect to other products or services that impair public health. Yet recent case law cautions that the First Amendment may be an increasingly high hurdle to overcome with respect to such restrictions.<sup>45</sup> The FDA's proposed graphic warnings for cigarette packaging were recently struck down on First Amendment grounds, the trial court eschewing the *Central Hudson* commercial speech test in favor of strict scrutiny review.<sup>46</sup> In addition, the Supreme Court recently struck down two public health laws on First Amendment grounds, one involving age restrictions on violent video games and the other restricting the use of pharmacy data to prevent access to physician-specific prescribing information.<sup>47</sup> While a careful reading of these cases reduces the concern about their impact on marketing and advertising restrictions on tobacco or other products that

cause harm to public health,<sup>48</sup> the flurry of cases concerning public health regulation and the First Amendment dictates that public health lawyers stay abreast of the issues and counsel their clients accordingly. Those seeking commercial speech regulation must clearly articulate the purpose for the regulation and demonstrate with sound evidence how the restriction will achieve that purpose. Public health lawyers should be mindful to track this First Amendment jurisprudence.

## Conclusion

The tobacco regulation movement shows how law and policy change can enhance traditional public health strategies and provides insight into how public health officials might use the law to address other persistent or emerging public health problems. Looking to local regulators for novel and aggressive action may be the most expeditious and effective approach to improving public health through law change. Tax policy might also be used to improve public health by discouraging use of harmful products or encouraging use of particularly beneficial products. Attorneys assisting public health professionals and local legislators should be aware of potential preemptive legislation and be prepared to fight such provisions. Public health lawyers should also become familiar with recent decisions involving First Amendment challenges to public health laws, track the pending cases involving the FDA's graphic warnings, and prepare legislation and supportive materials that best position the legislation should a First Amendment challenge arise.

One of the most powerful tools in public health is collaboration. When lawyers gain an understanding of public health issues and educate themselves on the legal framework within which law might improve public health, they can work collaboratively with the public health community to bring about positive change.

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# Merging Catholic and Non-Sectarian Hospitals: New York State Models for Addressing the Ethical Challenges

By Lois Uttley, Sheila Reynertson, Ronnie Pawelko, Sylvia A. Law, Patricia Hasbrouck and Kathryn Gottschalk

In New York, as elsewhere in the nation, community hospitals are exploring the potential for mergers, affiliations and other forms of business partnerships. The goal is to improve their bottom lines and position themselves to best advantage in a changing health care marketplace. Negotiating such partnerships can be challenging, especially when one of the partners is a Catholic-affiliated hospital or health system that restricts the provision of medical care deemed to violate Catholic teaching.

In recent years, several proposed Catholic/non-sectarian hospital partnerships in New York State have addressed ethical conflicts over the provision of health care services. Each of the outcomes has been unique, shaped by particular community needs and by such factors as the relative financial position of the merging partners and the commitment of the non-sectarian hospital's leadership to find ways of preserving patient access to reproductive health services threatened by the introduction of religiously based restrictions. In some cases, innovative approaches have emerged that could serve as lessons for future Catholic/non-sectarian hospital partnerships in New York and other states.

With grant support from the New York State Health Foundation and the Robert Sterling Clark Foundation, the authors have been studying and documenting these cases for a forthcoming briefing paper. This article describes and compares two of these approaches: the creation of an outpatient surgery center and the establishment of a "hospital-within-a-hospital" or co-located hospital. The article describes the process by which each of these approaches was developed, and compares their strengths and weaknesses. The authors also discuss the role of the New York State hospital oversight system.

## Issues in Catholic/Non-sectarian Hospital Mergers

Catholic-affiliated hospitals, like all non-profit hospitals, are accountable to their boards of directors and sometimes to larger health systems of which they are members. Like other hospitals, they must answer to state regulators who grant hospital licenses and federal regulators who certify hospitals as eligible to receive Medicare and Medicaid reimbursements. But what sets Catholic hospitals apart, even from other faith-based health care providers, is their accountability to the religious orders that are their sponsors and to local Catholic Bishops and ultimately, the Vatican.

While all hospitals have ethics policies and committees, Catholic hospitals also are guided by the *Ethical and Religious Directives for Catholic Health Care Services*<sup>1</sup> (*Directives*), which are promulgated and updated by the U.S. Conference of Catholic Bishops. These *Directives* spell out general principles for Catholic health care delivery, and specifically prohibit or restrict the provision of certain reproductive health care services: contraception, emergency contraception, sterilization, abortion, infertility services and comprehensive "safer sex" counseling to prevent the transmission of sexually transmitted diseases.<sup>2</sup> Each local Bishop has the responsibility for interpreting how the *Directives* are applied at Catholic health facilities in his Diocese. On occasion, these Bishops are overruled by the Vatican.<sup>3</sup>

When Catholic hospitals seek to partner with non-Catholic health facilities, future adherence to the *Directives* by one or both of the merging entities becomes a point of negotiation, and potentially a significant hurdle. If the non-Catholic hospital is asked to follow the *Directives*, there may be opposition from that hospital's medical staff, board of directors and patients, because the merger could then cause a loss of access to services in a community and could require physicians to follow religious guidelines that may conflict with prevailing medical standards of care and the ethical principles of health care professionals.<sup>4</sup> Staff of the non-Catholic hospital also could lose their employee health insurance coverage for contraception, sterilizations, abortions and infertility services through the merger.<sup>5</sup> On the other hand, if the Catholic hospital agrees to allow the non-Catholic facility to continue providing a full range of services, including those prohibited by the *Directives*, there is a strong possibility that the local Bishop will disapprove the transaction.

## New York State Hospital Oversight

New York State's hospital oversight system has played a role in ensuring continued community access to reproductive health services as the hospital industry has consolidated, although this article suggests that patient protections should be strengthened. New York's Certificate of Need (CON) process governs the purchase of major medical equipment, renovation and construction of health facilities and the establishment of health facilities, which includes the sale or merger of health facilities. New York has several levels of review, with the intensity of re-



view, ranging from administrative review to full review, dependent on the type of application. Establishment applications undergo full review, which involves the highest level of scrutiny.

The CON process, however, responds to hospital-initiated proposals and does not cause hospital consolidation. In 2005, the New York State Legislature and Governor George Pataki created the Commission on Health Care Facilities in the 21st Century, known as the Berger Commission after its chairman, Stephen Berger.<sup>6</sup> The Commission was charged with “examining the system of general hospitals and nursing homes in New York State and recommending changes to that system.”<sup>7</sup> The intent in establishing the Commission was to reconfigure and “rightsize” New York’s hospital and nursing homes in order to eliminate excess capacity and to ensure that regional needs would be met as health care delivery changed.

The core finding that emerged from this process was that many regions of New York had an over-supply or mal-distribution of acute care hospital beds and technology that generated wasteful costs and poor quality. The final recommendations, which became law on January 1, 2007, affected 57 hospitals—one quarter of the state’s hospitals—calling for 48 reconfigurations, affiliations or realignments and the closure of nine hospitals, eliminating approximately 7% of licensed hospital beds in the state.<sup>8</sup>

Of the affiliations recommended by the state hospital commission, four involved partnerships between Catholic and non-sectarian hospitals. Two of those four, the Kingston case discussed in this article and the merger of three hospitals in Schenectady County, were implemented largely as recommended.<sup>9</sup> Another Commission-recommended merger of Catholic and non-sectarian hospitals in Niagara Falls did not result in a successful partnership.<sup>10</sup> A fourth recommended merger, in Elmira, did not occur immediately, but ultimately did take place.<sup>11</sup>

Several other partnerships between Catholic and non-sectarian hospitals have occurred in New York State in recent years without a specific mandate from the Berger Commission. One of those transactions involved hospitals in Troy, NY, and is the subject of our second case study.

### **First Case Study: Kingston, New York**

Non-sectarian Kingston Hospital and Catholic-affiliated Benedictine Hospital are located less than a mile apart in Kingston, NY, which has a population of 22,000. Kingston Hospital historically provided a full range of women’s reproductive health services, including abortions and tubal ligations. The two hospitals had at-

tempted to merge in 1997 in a proposed partnership that also included non-sectarian Northern Dutchess Hospital across the Hudson River. That proposed transaction fell apart in 1998 amid vehement community opposition to plans for Kingston and Northern Dutchess hospitals to discontinue provision of reproductive health services that violate Catholic teaching. Anti-trust concerns raised by the Federal Trade Commission and differences in culture and management style among the three hospital boards of directors and CEOs also played a role.<sup>12</sup>

Following that failed merger attempt, Kingston Hospital officials held focus group discussions with community residents about the future of the hospital, and in 1999 they unveiled a new hospital mission statement that underscored its non-religious mission.<sup>13</sup>

Kingston and Benedictine hospitals began looking at each other again as financial stresses mounted at both facilities. Both hospitals were operating at only 70 percent of capacity, and offering duplicate services. Michael Kaminski, who became CEO of Kingston Hospital in 2004, recalled that “we recognized the reality of the situation. We were really going to have to do something.”<sup>14</sup> However, given the acrimony left over from the previous merger attempt, “the boards of both hospitals were reluctant to make another attempt at merging,” Kaminski said.

In 2004, the boards and management of both hospitals undertook new negotiations with the understanding that: 1) the missions of both hospitals had to be preserved, 2) a plan had to be developed to realign services to avoid duplication, 3) abortions and sterilization services had to continue to be available to the community, and 4) neither hospital could appear to have taken over the other. Throughout the hospitals’ negotiations, discussions were held with the NYS Department of Health and the Berger Commission, according to Kaminski. Women’s health advocates met separately with Commission leadership and testified at commission-related public hearings about the need to protect reproductive health services.

The Commission’s report recommended that Kingston and Benedictine hospitals come together under one unified governance system and reduce their combined capacity from 385 beds to 300 or fewer. The report summary asserted that this reconfiguration “will improve the financial standing of both facilities, reduce duplication of services, allow for efficient future investments, and improve the organization’s ability to meet the community’s health care needs.”<sup>15</sup> Should the hospitals find themselves unable to merge after one year, the Berger Commission recommended lifting the operating license of one of the hospitals, without saying which one it should be. In recognition of the conflict over reproductive health services that had stymied the previous merger, the Berger Com-

mission specified that the Kingston-Benedictine partnership should be “contingent upon Kingston Hospital continuing to provide reproductive health services in a location proximate to the hospital.”<sup>16</sup>

The hospitals agreed to create a joint parent, Health Alliance, a non-sectarian entity that includes Kingston and Benedictine hospitals. Each hospital remained a separate corporation, and no hospital achieved majority control of the Health Alliance board. Initially, the parent organization was legally “passive” to allow Kingston Hospital to maintain abortion services until a plan could be carried out to move abortions to another location, under the auspices of a separate corporation. “The reason for the passive parent was...the Catholic Church would not allow Benedictine to follow any dictates of this parent corporation until and unless Kingston discontinued abortion services,” Kaminski said.<sup>17</sup> Once that was accomplished, the “passive” parent would become an “active” parent over the hospitals. Each of the hospital’s boards would report to and be responsible to the “active” parent, but each hospital would continue to maintain separate operating certificates and financials under the “active” parent arrangement. The passive phase of the partnership did not require state approval, but the active parent arrangement did.

After much negotiation, and consultation with the Archdiocese of New York, the two parties developed a memorandum of understanding that expressly permits Kingston Hospital to continue to provide post-partum tubal ligations, contraception and contraceptive counseling, treatment of ectopic pregnancies and miscarriage management. Community pressure was exerted through in-person meetings with hospital officials and through intervention in the State Department of Health’s Certificate of Need regulatory proceedings. The continued provision of post-partum tubal ligations (either at the time of cesarean delivery or immediately following a normal delivery) was accepted by the Catholic partner by defining that service as merely a “continuation of procedure” that had already begun with the initiation of childbirth.

However, abortions, “interval” tubal ligations (those not performed immediately after childbirth) and vasectomies could not be continued in Kingston Hospital because of Catholic objections. The hospital historically had performed first-trimester abortions, largely for low-income women without other easily available alternative providers.<sup>18</sup> Continued provision of those reproductive services was made possible with the establishment of a new 5,500 square-foot outpatient ambulatory surgery center, located in the parking lot of Kingston Hospital, just steps away from a hospital entrance. The Foxhall Ambulatory Surgery Center has its own board of directors and is legally distinct from Kingston Hospital.

This solution was the result of many months of contentious negotiations. The Archdiocese would not accept an early plan that placed abortion services within a “carved-out” separately incorporated section of Kingston Hospital itself, according to Kaminski.<sup>19</sup> Proposals to place the services within a suite in a medical office building were turned down by doctors with offices in the building, who were worried about protestors creating disruptions, and by community members who were concerned about the safety of women seeking abortion care in an unsecured building. By constructing the surgery center in the parking lot of Kingston Hospital, the hospital better assured that it could maintain security on its own land.

Kingston Hospital officials working to create a business plan for the surgery center decided to offer a range of other non-reproductive ambulatory surgeries for two reasons: 1) to better ensure financial viability of the center, which otherwise would have to survive solely on the revenues from a narrow range of reproductive health services; and 2) to protect the safety and privacy of women seeking care there by making it impossible to tell which service they were seeking. Community members and women’s health advocacy groups approved of this mixed-menu of services, but expressed concerns at state hospital review hearings that the center still appeared financially vulnerable over the long term.

To pay for construction of the Foxhall Center, Kingston Hospital officials turned to the state. They were able to secure more than \$4 million for the center as part of a larger \$47 million grant the State Health Department made available to help Kingston and Benedictine carry out a number of changes necessary to bring about the partnership.<sup>20</sup> When meeting with state officials, Kaminski recalls, Kingston Hospital representatives “tried to make it clear that, without state funding, the realignment of services and creation of the parent corporation and ambulatory surgery corporation could not occur.”<sup>21</sup>

The next challenge was to address objections from Benedictine and the Archdiocese to plans to staff the Foxhall Center by leasing staff from Kingston Hospital. This hurdle was overcome by transferring some hospital staff to the payroll of an unaffiliated entity, Nistel, Inc., which employs staff and leases them back to the ambulatory surgery center and the two hospitals. These staff work a few days a week in the ambulatory surgery center and the rest of the time in the two hospitals. The transfer of staff is intended to insulate Benedictine from any involvement in having its staff going to the ambulatory surgery center and providing services forbidden by the Catholic *Directives*.

How is the Kingston solution working? All maternity services from the two hospitals have been consolidated at Kingston Hospital, which continues to perform postpartum tubal ligations. The Foxhall Center remains open, but only two to four days a week, and with a limited range of non-reproductive services. Financial viability remains a concern. Most troubling was the news that the physician who had provided abortions at the Foxhall Center retired in late 2011 and a replacement was not secured for eight months. The announcement in May 2012 that one of the hospitals might be closed due to continuing financial problems raised additional community concerns.

### **Second Case Study: Troy/Albany, New York**

Troy is home to New York State's first "hospital-within-a-hospital" or "co-located hospital" solution created to preserve access to key reproductive health services at a non-sectarian hospital ahead of a planned merger with two local Catholic hospitals. The Burdett Care Center is an independent, separately licensed 15-bed maternity hospital located on the second floor of the historically non-sectarian Samaritan Hospital. The facility consolidates all maternity services from Samaritan Hospital and nearby St. Mary's Hospital and preserves services that can no longer be offered by Samaritan itself, under the terms of the merger: sterilization procedures, birth control and treatment of certain pregnancy emergencies.

In the early 1990s, Troy, NY, supported three hospitals: two non-sectarian facilities, Leonard and Samaritan, and a Catholic hospital, St. Mary's. In 1994, St. Mary's merged with Leonard, creating Seton Health System, a Catholic-sponsored entity, and St. Mary's was the surviving hospital. Women who had depended upon Leonard's outpatient clinic for contraceptive services were turned away. A lawsuit was filed by reproductive health organizations in 1995 asserting that the State failed to adequately consider public need when approving the merger and contending the merged hospital's refusal to counsel and refer patients for contraceptive care violated standards of care. The lawsuit was eventually settled, with the hospital agreeing to allow physicians to counsel patients about contraception and provide patients with a list of providers who offered contraceptive care. The settlement also explicitly allowed physicians to follow up with the patient to ensure needed care was received and to include such information in patients' medical records.<sup>22</sup> The most significant benefit to this approach was it set an expected minimum standard for future such affiliations.

A decade later, one of the two remaining hospitals in Troy—Samaritan Hospital, which was part of the non-sectarian Northeast Health system—began to actively consider its options. The CEO of Northeast Health, James

K. Reed, M.D., began talking to the CEO of St. Peter's Health Care Services, a Catholic health system in nearby Albany. "The organizations were not in a current financial bind," Dr. Reed recalled, "but we believed the future was fundamentally going to change for the community hospital."<sup>23</sup>

When officials of St. Mary's Hospital (the other remaining hospital in Troy)—learned that Northeast Health was in talks with St. Peter's, they asked to be involved as well. Women's health advocates became concerned that a merger of Samaritan Hospital with St. Mary's Hospital could eliminate hospital provision of reproductive services completely in Troy, if Catholic health restrictions became applied to Samaritan Hospital. Months of negotiations between the merger partners, and conversations with the women's health advocates, then took place.

The result was the creation of a new independent maternity hospital—the Burdett Care Center—carved out from the second floor of Samaritan Hospital in Troy in order to maintain community access to sterilizations and contraception. This case has a number of characteristics which highlight the complexities of working around religious restrictions.

The new parent corporation of the merged hospitals, St. Peter's Health Partners, is a non-sectarian entity in which corporate "members" St. Peter's and Seton Health retain their identities as Catholic facilities and member Northeast Health (including Samaritan Hospital) retains its identity as a non-sectarian health care system. As a condition of the agreement, however, Northeast Health agreed to abide by Catholic health restrictions, and despite its non-sectarian identity, banned abortions, tubal ligations, contraceptive counseling and other reproductive health services within Samaritan Hospital.

The creation of the Burdett Care Center as a separately licensed entity ensures the continuation of these reproductive health services at the location of Samaritan Hospital, with the exception of elective abortions which were banned at both Samaritan and Burdett Care Center at the request of Northeast's Catholic merger partners. Local providers outside the hospital setting have agreed to absorb the small number of abortion cases that were routinely performed at Samaritan prior to the merger.<sup>24</sup> Those cases that require hospitalization are referred through an existing network to nearby Albany Medical Center. The New York State Department of Health provided \$5 million in grant funding to help create the center.<sup>25</sup> Prior to merger, Samaritan also created a \$5 million trust for the Burdett Care Center as a financial buffer.<sup>26</sup>

Establishing the Burdett Care Center was a complex endeavor that consumed months of the time of Northeast Health executives, one of whom later said that this ap-



proach is “not for the faint of heart.”<sup>27</sup> The Burdett Care Center has its own staff and board. Board members include an obstetrician-gynecologist and an attorney who has been active in support of reproductive rights, as well as a midwife. Midwives, who had played a larger role at St. Mary’s maternity unit than at Samaritan’s, demanded and got changes to the Center’s physical configuration and policies to accommodate their approach.

In the last month before the opening of the center, Burdett Care Center officials faced challenges in overcoming some unexpected regulatory demands by the Regional Office of the Centers for Medicare and Medicaid Services (CMS). Very late in the process, Burdett Care staff were informed that CMS would strictly interpret federal regulations that help to define a “separate and distinct” health care facility. Issues regarding 24-hour specialist care, medical record keeping and EMTALA obligations had to be ironed out before a final stamp of approval could be given. With some adjustments to its plans, the Center passed this final roadblock and was given CMS approval, which is needed in order to receive Medicare reimbursements.

In offering advice to other systems considering a hospital merger, Dr. Reed said, “Know your stakeholders and be as open and transparent as you possibly can be, so that the community can help you through this process.”<sup>28</sup>

## Lessons Learned

Preservation of community access to reproductive health services in Troy and Kingston was achieved only with considerable investments of time and money, including nearly \$10 million in public funds. What lessons can be drawn from these two cases?

First, executives and boards of the non-sectarian hospitals shouldered primary responsibility for devising solutions to preserve access to reproductive health services—in one case through creation of an ambulatory surgery center and in the other through establishment of a co-located, separately licensed maternity hospital. The leaders of the non-sectarian hospitals spent countless hours negotiating every detail of the arrangements with their prospective Catholic hospital partners. They also met repeatedly with community members and representatives of women’s health organizations, responding to questions and critiques. Finally, they navigated regulatory requirements at the state level and, in the case of Troy, surmounted unexpectedly complicated federal requirements.

Second, the development of such case-specific solutions demands extraordinary vigilance and engagement by volunteer members of the concerned community. In

Kingston, community members actively monitored merger talks between the two hospitals for more than a decade, helping defeat a first merger attempt that would have sacrificed some reproductive services and building public pressure for protection of these services. When the Berger Commission mandated a Kingston merger, community activists worked with hospital executives to shape the creation of the Foxhall Ambulatory Surgery Center. In both the Kingston and Troy cases, professionals at women’s health advocacy organizations and community activists devoted many hours to analyzing the hospitals’ proposals and submitting comments to hospital executives and to state regulators. This level of commitment and resources is not available in many communities.

Third, despite all of this effort and money spent, each of the two solutions is imperfect. Abortion services were preserved in Kingston, but not Troy, and abortions recently lapsed in the Kingston surgery center after its only provider retired and he was not replaced for eight months. Kingston Hospital managed to preserve post-partum tubal ligations within the hospital, while sending “interval” tubal ligations and vasectomies to the surgery center in its parking lot. In Troy, all sterilization services were removed from Samaritan Hospital and placed in the Burdett Care Center.

Each of these solutions involved divorcing key women’s reproductive health services from the non-sectarian hospitals in which they had long been delivered, and placing those services in separately incorporated health facilities. The long-term financial viability of such separate centers remains uncertain, because they have a narrow range of services generating revenue, and expansion of their service menus would potentially place them in direct competition with the hospitals that created them. Kingston’s ambulatory surgery center, in particular, appears financially vulnerable. Creators of the Burdett Care Center in Troy took steps to protect it from losses by establishing a \$5 million trust, and providing revenues from an expected 1,200 births per year.

These transactions have accomplished financially desirable hospital consolidation, while satisfying ethical differences and, at least initially, protecting community access to all or most reproductive health services. However, the long-term costs of these approaches have not been thoroughly examined. We encourage hospital regulators to actively monitor these two cases and intervene when necessary to ensure that access to reproductive care is preserved. Moreover, we urge public policymakers to examine the shortcomings of these two approaches and explicitly address the need for long-term assurances of community access to reproductive health services.

## Endnotes

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5. Employees of Catholic-affiliated hospitals should gain contraceptive coverage after August of 2013, the deadline set by the U.S. Department of Health and Human Services for religiously affiliated employers to come into compliance with new women's preventive services coverage requirements promulgated by HHS under the authority of the Affordable Care Act.
6. The Commission consisted of 18 statewide members and six regional members who represented different regions of the state. Six regional advisory committees developed non-binding recommendations to reconfigure their region's hospitals and nursing homes to meet regional needs. The authorizing legislation directed the Commission to consider factors that included: the need for capacity; the existence of other health care services in each region; and the extent to which the facility in question served the health care needs of the region, including serving Medicaid recipients, the uninsured and underserved communities.
7. *2005 Interim Report Statewide Comprehensive Plan for Mental Health Services*, New York State Office of Mental Health (Nov. 2005), <http://omh.ny.gov/omhweb/Statewideplan/2005/interimreport/>.
8. In response to the Commission report, the state Senate and Assembly held public hearings to gather input from interested and affected parties. Pursuant to the enacting legislation, the legislature could only vote down the report in its entirety or accept it. Although there was significant opposition to many of the Report's specific recommendations, the Legislature chose not to reject it down. With the state legislature's refusal to act, the recommendations of the Berger Commission became legally binding mandates on January 1, 2007.
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10. *Report on Implementation of the Report of the Commission on Health Care Facilities in the Twenty-First Century*, New York State Department of Health, p.80 (November 2007), [http://www.nyhealth.gov/facilities/commission/docs/implementation\\_of\\_the\\_report\\_of\\_the\\_commission.pdf](http://www.nyhealth.gov/facilities/commission/docs/implementation_of_the_report_of_the_commission.pdf).
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22. Patricia Donovan, *Hospital Mergers and Reproductive Health Care*, Family Planning Perspectives (Nov/Dec 1996), <http://www.guttmacher.org/pubs/journals/2828196.html>.
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25. *Id.*
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27. Interview with James Reed, M.D. and Susan McDonough, p. 18.
28. Interview with James Reed, M.D., p. 2.

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# Obesity: Solving an Epidemic through Public Policy and Education

By Michael A. Hernández

Obesity is a recognized public health problem, both in the United States and around the world. It has received increasing attention in the media both in print and through other forms of media coverage such as public broadcasting, Facebook and Twitter. The obesity epidemic and what we need to do about it have rapidly become part of our national consciousness.

If you Google “Obesity in America,” you may be surprised with your search query results—about 34,900,000, depending on your search engine, and news trending that day. But it’s not the number of stories that is astounding. It’s the message that these stories are delivering. We, as a nation, are effectively eating ourselves to death by way of obesity-related illnesses, which are mostly preventable.

However, there are many health professionals who will argue that we are actually starving ourselves to death. Starving? How can that be? There’s an obesity epidemic going on. So how can we be starving ourselves to death?

Good question. How can a nation be starving itself to death if its collective waistline keeps expanding? The answer is a complex one and one that requires a more thoughtful consideration. First and foremost, we need to consider what we mean by starvation. Do we mean “to die from lack of food,” or is it “to be deprived of something necessary?” By all accounts we’re eating more, and yet, our bodies are breaking down. Why is this occurring? Could it be that our bodies are being deprived of something necessary to sustain good health? And if so, what might that be? Do I need to take vitamins? Do I need to eat better?

Yes, we all do. Rather, we all need to eat more nutrient-dense foods, such as fruits, vegetables, nuts, whole grains, fish and lean meats, which contain vital nutrients and vitamins that are necessary for good health and well-being.

However, the amount of food we’re eating is only part of the problem. Other things to consider are the types of foods we are eating, and the accessibility to healthy foods versus unhealthy foods—all concerns of public health officials, as well as many health professionals around the world. Here in the City of New York the Public Health Association of New York City (PHANYC) in concert with the New York City Department of Health and Mental Hygiene (NYC DOHMH), and with numer-

ous other health agencies, work to advocate for access to affordable healthy foods for all New York residents. In doing so PHANYC and the NYC DOHMH have led the charge in bringing healthier foods into the schools, the bodegas, and to underserved communities throughout the five boroughs. Over the past five years PHANYC has advocated for policies to help end food desserts and to reverse obesity in New York City.

## What Is Obesity?

According to recent data, more than two-thirds of adults over 20 years of age (more than 72 million people) are either overweight or obese<sup>1</sup>; or more than one-third of children ages 10–17 are obese (16.4 percent) or overweight (18.2 percent).<sup>2</sup>

But when we talk about obesity and obesity-related disease, what are we really talking about? How do we define obesity, and has it always been a problem?

Generally speaking, overweight and obesity are both labels for ranges of weight that are greater than what is generally considered healthy for a given height. The terms also identify ranges of weight that have been shown to increase the likelihood of certain diseases and other health problems. A more technical definition for obesity would be a weight at least 20% above the weight corresponding to the lowest death rate for individuals of a specific height, gender, and age—or, ideal weight. For example, 20 to 40% over ideal weight is considered mildly obese; 40-100% over ideal weight is considered moderately obese; and 100% over ideal weight is considered severely, or morbidly obese. More recent guidelines for obesity use a measurement called BMI (body mass index), which is the individual’s weight, multiplied by 703 and then divided by twice the height in inches. BMI of 25.9-29 is considered overweight; BMI over 30 is considered obese. Measurements and comparisons of waist and hip circumference can also provide some information regarding risk factors associated with weight—the higher the ratio, the greater the chance for weight-associated complications.

But what is an “ideal weight”? Surely there are allowances for varying body types, muscular development, age, gender, and overall well-being?

The short answer is yes, there are. Even the use of BMI is not a completely accurate measure of one’s health



or risk to weight-associated complications. It is merely a baseline, much like the USDA recommendation of 2000 calories per day. Still, within these variances of ideal weight lies the question of what is the ideal weight for me? Simply falling into an acceptable spectrum of weight for one's age, height, and gender is not enough. Equally important in achieving good health, and maintaining a healthy weight, is exercising regularly.

In 2004, the U.S. Centers for Disease Control and Prevention (CDC) ranked obesity as the number one health risk facing America. And it was with good reason. Slowly but steadily the prevalence of obesity in America has grown dramatically over past twenty years, 1985 to 2010. So much so that if the current trend of obesity continues, half of American adults will be obese by the year 2030. The CDC recommends that adults should get at least 2 hours and 30 minutes (150 minutes) of exercise a week—a combination of moderate-intensity aerobic activity (i.e., brisk walking) and muscle-strengthening activities on 2 or more days a week, working all major muscle groups (legs, hips, back, abdomen, chest, shoulders, and arms). Many groups, such as the National Football League (NFL), the National Dairy Council, and the White House, to name a few, have all launched physical activity and nutrition programs geared to children and their families with the hopes of reversing the obesity tide.

## Risks Associated with Obesity

In 2003 the CDC released a report that revealed that one in three children born in the U.S. in the year 2000 will go on to develop Type 2 diabetes—formally known as adult onset diabetes—at some point in their lives.<sup>3</sup> A 2005 report, published in *The New England Journal of Medicine*, said, “the prevalence of obesity, especially among children, is likely to continue to rise; with obesity occurring at younger ages, the children and young adults of today will carry and express obesity-related risks for more of their lifetime than previous generations have done.”<sup>4</sup> These two reports alone sent a single message to the American public that, for the first time in two centuries, the current generation of children in America may have shorter life expectancies than their parents, by as much as five years.

The simple fact of the matter is obesity and obesity-related diseases—heart disease, stroke, Type 2 diabetes, hypertension, and some forms of cancers—are indeed a big problem. And unfortunately the problem is only getting worse every year.

Obesity is one of the most challenging health crises the country has ever faced—both as a health burden and as a financial burden. According to a 2009 economic analysis published in *Health Affairs*, obesity-related medi-

cal costs total \$147 billion a year, accounting for nearly 10 percent of all annual medical spending. The report goes on to say that obese people spend 42 percent more on health care costs than healthy-weight individuals and that childhood obesity alone is responsible for \$14.1 billion in direct costs.<sup>5</sup>

Of the \$147 billion in direct medical costs, Medicare and Medicaid pick up the tab for \$61.8 billion. Annually, the average total of health expenses for a child treated for obesity under Medicaid is \$6,730 while the average cost for all children under Medicaid is \$2,446—more than two-and-half times the cost.

But these are just the direct cost. Obesity-related job absenteeism costs the country around \$4.3 billion annually, lower productivity costs are estimated at \$506 per obese employee per year, and as a person's body mass index increases, so do the number of sick days, medical claims, and health care costs.

But more importantly is the cost in human lives lost due to obesity and obesity-related diseases.

In an article written for the W.K. Kellogg Foundation in my capacity representing the New York City Food and Fitness Partnership, I cited a CDC report, in which it stated that there were more than 110,000 deaths every year in the U.S. caused by obesity.<sup>6</sup> Furthermore, according to the NYC DOHMH, 56% of adults and more than 40% of elementary school children living in New York City were either overweight or obese. In the last decade alone, the number of New Yorkers diagnosed with diabetes had increased by 250% and the number of deaths from diabetes had nearly doubled.

However, a report released by the U.S. Department of Health and Human Services (HHS) attributes unhealthy eating and inactivity as a contributing cause to 310,000 to 580,000 deaths each year in America. That's 13 times more than are killed by guns and 20 times more than are killed by drug use.<sup>7</sup>

These numbers are alarming, however not as alarming as who is affected the most by obesity and the chronic diseases associated with it—Blacks, Latinos, and those who are low income.

## Cost of Being Poor in America

Nationally, households that make less than \$15,000 have a 33.8 percent obesity rate. This reported rate is followed closely by rates for households that make between \$15,000 and \$25,000 (31.8 percent), \$25,000 and \$35,000 (29.7 percent), and \$35,000 and \$50,000 (29.5 percent), whereas households that have an income above \$50,000 have a 24.6 percent obesity rate.<sup>8</sup>

For New Yorkers living in poor areas of the city, where fast food restaurants and take-out shops are abundant, unhealthy food options make eating healthily extremely difficult. Unfortunately for many people living on a fixed income, it is the unhealthy foods—which tend to be less expensive than healthier food options—that become their choice by default, effectively forcing them to choose items that can lead to health problems over time.

In 2008 PHANYC and the City University of New York Campaign Against Diabetes released a report titled *Reversing Obesity in New York City: An Action Plan for Reducing the Promotion and Accessibility of Unhealthy Food*.<sup>9</sup> The goal of this report was to educate and spark debate on food policy choices for New York. One of its key findings was that the portion sizes of many unhealthy products had grown over the years. This perceived bargain of more bang for your buck allowed food vendors to sell larger portions for only a few pennies more than the smaller size—hence, leaving customers feeling as if they just got a deal. Common examples of this practice are McDonald's "Super Size Me" and "Extra Value Meals."

Another key finding was even though consumers knew they were eating food high in sugar, fat, and sodium, which increases their risk of disease, many continued to choose the unhealthy foods because of convenience, tastes satisfaction, and low costs. In many cases, these desirable characteristics of unhealthy food are the direct consequence of food industry marketing, product design, and pricing practices.

I refer to this as the food industry's holy trilogy: packaging design, marketing, and pricing. The driving forces behind consumer demand are to create the desire, offer the illusion, and then sell it at a seemingly reasonable price, all the while making a huge profit. Truth be told, the greatest expense in most package food is the marketing campaign followed by packaging itself. Usually the product costs relatively nothing to produce. For what we pay for we should probably eat the wrapper and toss the product. The nutritional value would be negligible but you'd probably get more fiber out of it.

Of course the problem with dispelling the illusion is there's always another waiting to replace it, and with it the promise of "better than before" or "more for your money."

A far bigger problem facing public health officials is the cost of mounting each education campaign. It is impossible to go toe-to-toe with the major food manufacturers. Their pockets are too deep, and their advantages too many—consumer loyalty, marketing budgets that exceed what the federal government can afford, and the ability to reinvent themselves, i.e., Coca-Cola Company and its diverse product line that includes "healthier bev-

erage options" such as Vita water, Tropicana Juices, and sports drink POWERADE.

When you consider that the federal government's largest nutrition education program for the general public—the 5 A Day program—has an annual communications budget of about \$3.6 million,<sup>10</sup> whereas Mars spends 68-times that to promote M&Ms candies (\$68 million),<sup>11</sup> while McDonald's spends 1000-times more than 5 A Day on advertising and promotions (\$1 billion) annually, it leaves little doubt as to why American consumers find it so difficult to make the healthy choice. The federal government's message cannot be heard through the roar of giant food manufacturers' big budget commercial campaigns.

## So How Do We Fight an Uphill Battle?

In the *Trust for America's Health* annual report, *F as in Fat: How Obesity Threatens America's Future 2011*, former Surgeon General Dr. David Satcher, M.D., Ph.D., offered this personal commentary:

In the Surgeon General's report (2001), I wrote that the obesity crisis would not be solved by treating it as a personal failing on the part of those who weigh too much. This is still true. We must realize that our predicament cannot be solved through individual action alone.

Both the public and private sector must pitch in to ensure that we live in a society where gaining weight becomes more difficult and maintaining a healthy weight becomes easier.

Right now, our society makes it especially hard for some groups not to gain weight. More than 20 million Americans, most of them poor, live in "food deserts," areas that lack nearby full-service supermarkets selling fresh fruits and vegetables. People who live in these areas must often make do with corner and convenience stores, which encourages them to eat more of the low quality, fattening foods that can lead to weight gain. Millions live in unsafe neighborhoods, or areas with few parks and playgrounds; as a result, they often have few opportunities for physical activity.

One key is prevention. We must teach children to eat well before they begin drinking sodas for breakfast. School cafeterias must feed children more nutri-

tious food. School districts must increase physical education so that students burn more calories and learn the habit and joy of physical activity.<sup>12</sup>

As previously mentioned, PHANYC has long stood with our New York partners in health—the New York State Department of Health (NYS DOH), and the New York City Department of Health and Mental Hygiene—as well as with our national partners—the American Public Health Association (APHA), and the United States Department of Health and Human Services (HHS)—to promote policies and programs to help all New York and U.S. residents to live healthier lives.

Whether actively advocating for legislation such as the Affordable Care Act (ACA), which provides a number of opportunities to enhance obesity prevention efforts—through the Prevention and Public Health Fund, Community Transformation Grants, expanding benefits and coverage of preventive services, nutrition labeling, programs by the Center for Medicare and Medicaid Innovation, and the Children’s Health Insurance Program—to supporting the Healthy, Hunger-Free Kids Act, PHANYC has shown its commitment to fighting for policies and programs that can have a significant impact on obesity, nutrition, and physical activity policies in the United States.

Here in New York City PHANYC continues to be a driving force helping to support programs initiated by the NYC DOHMH, the Department of Transportation (DOT), and the Department of Parks and Recreation (DPR). We have promoted DPR programs, such as: Walk NYC, which is a free program that encourages New Yorkers of all ages to get fit while enjoying the outdoors; Shape Up NYC, which offers free fitness classes every week at dozens of locations across the five boroughs; and BeFitNYC, a search engine for free and low-cost fitness activities in New York City.

PHANYC has also played a pivotal role in supporting DOHMH initiatives like: the Adopt a Bodega, a Healthy Bodegas initiative that helps local stores to increase healthy offerings, like fresh fruits and vegetables, whole grain bread, low-fat milk, and low-salt and no-sugar-added canned goods; the Green Cart program, which brings fresh fruits and vegetables into low-income neighborhoods that have been classified as food deserts, and helping new entrepreneurs establish a business of their own; and EBT acceptance at Farmer’s Markets all over the City of New York.

With the DOT we have advocated to create more bike lanes to allow for safe cycling routes to encourage physical exercise; open up more public plazas to increase

physical activities; street closings in select neighborhoods in the South Bronx, East and Central Harlem, and parts of Central and North Brooklyn to allow communities a safe place to engage in physical activities; and school-yard playgrounds to make recreation more accessible for neighboring community residents.

Together with our City, PHANYC is working to help make the healthy choice the easy choice for all New Yorkers.

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# New Directions in Palliative Care: Interdisciplinary Perspectives—Clinical Practice and Public Health Law, Policy and Ethics

By Mary Beth Morrissey, Dana Lustbader and David C. Leven

## Introduction

Palliative care is interdisciplinary, specialized care for people with serious illnesses. In this article, we present perspectives that span clinical practice, public health law, and public health policy and ethics on the challenges of improving population health as well as palliative care delivery and implementation in a rapidly changing health care environment, and discuss directions at health department, local, state and national levels.

Understanding palliative care as a public health issue is a first step in advancing knowledge and promoting health and well-being at the population level for diverse groups of Americans who are at risk for chronic disease or who already suffer with serious illness and multiple comorbidities. The World Health Organization Public Health Model has been recognized by leading experts in the palliative care field, and has served as the foundation for development of an enhanced public health model that focuses on four key strategies for helping to embed palliative care into health care systems and communities: policy development, drug availability, health care worker and public education, and implementation of palliative care services.<sup>1</sup> Consistent with this model, public health prevention and intervention strategies that target development of a generalist-level palliative care workforce and palliative systems of care are likely to be effective in helping to achieve essential goals of health reform—better health, better health care, and reduced costs. Building collaboration among public health professionals and advocates and attorneys who are dedicated to improving public health will provide support to the growing evidence-based palliative care movement and its full integration into public health systems and networks.

## Clinical Practice Perspective: Meaningful Goals of Care Discussions

Palliative care is a type of care that is focused on providing patients with relief from the symptoms, pain, and suffering associated with serious illness—whatever the diagnosis. The goal is to improve quality of life for both the patient and the patient's family. Palliative care is appropriate at any age and at any stage in a serious illness, and can be provided together with curative treatment.

Palliative care may be provided for years prior to death or even for patients with curable but burdensome diseases like childhood leukemia or breast cancer.

Hospice care is end-of-life palliative care for the final six months of life. In order for a patient to qualify for the Medicare Hospice Benefit, a physician must certify that death is likely within six months if the disease runs its natural course. Hospice care is offered when curative treatments are unwanted or no longer beneficial. Patients can get hospice care at home, in a nursing home or an inpatient hospice unit. Hospice care is an underutilized resource, especially in New York where patients are often referred late in the course of their disease. Most patients in the New York metropolitan area return to the hospital for terminal care, even though their preferences may have been to die at home.

The story of Mr. A illustrates how palliative and hospice care can improve the quality of life for patients with serious illness by aligning treatments with patient preferences. Mr. A was a 44-year-old real estate investor when he was diagnosed with pancreatic cancer. He was married and had four children. He received chemotherapy and palliative care concurrently for over two years. The palliative care interventions focused on the treatment of his fatigue, constipation and abdominal pain. His disease eventually progressed and spread to his liver causing fluid to accumulate in his abdomen (e.g., ascites) which made his breathing difficult. His palliative care team drained the ascites monthly and prescribed medication to control his pain. When chemotherapy became too burdensome, it was discontinued and Mr. A was enrolled in home hospice care.

Home hospice provided Mr. A with four hours a day of a home health aide. The remainder of the care had to be provided by unpaid family caregivers. Mr. A's wife quit her job and devoted herself to the care of her husband which included bathing, careful spoon-feeding and changing soiled bed linens. Mr. A developed a blood clot in his left leg and was brought to an inpatient hospice unit where his pain and symptoms could be better managed. Once his symptoms were controlled, Mr. A was transferred back home where his increasing shortness of breath was treated with liquid morphine given under the tongue by his family caregivers. He died two weeks later.

surrounded by his wife, four children and a dedicated community from the local church.

Mr. A was fortunate to have an oncologist and palliative care team discuss his prognosis and the risks and benefits to treatments during each visit. His preferences for life-sustaining treatments were also discussed during his outpatient visits where Mr. A made his wishes known that he wanted to die at home. Quality of life was more important to Mr. A than quantity.

Why is Mr. A's story the exception? Most physicians lack the skills necessary for meaningful goals of care discussions regarding end-of-life preferences. It is simply "easier" to continue treatment, even when death is certain. The default for a patient like Mr. A is to get admitted to the hospital for acute episodes of deterioration and, for most Americans, to actually die in the hospital or nursing home, rather than at home. Failure to discuss preferences for treatments as the disease progresses results in unwanted or non-beneficial treatment. Failure to discuss preferences for treatments as the disease progresses results in unwanted or non-beneficial treatments which are estimated to represent about 30% of health care costs.

Who could benefit from palliative care? Suggested criteria for palliative care intervention include repeated hospitalizations for the same condition, complex pain or symptom burden, bedbound condition and metastatic cancer. Another useful tool is the "surprise question." Would you be surprised if the patient died within a year? If the answer is no, the patient is likely to benefit from a thoughtful goals of care discussion to ascertain preferences for treatments as the condition progresses.

Patients like Mr. A and others with multiple comorbidities are driving runaway medical spending. Although the seriously ill constitute only 5% of patients, they account for more than half of the nation's total healthcare costs. The 10% of Medicare beneficiaries with 5 or more co-morbid illnesses account for two-thirds of total Medicare spending. The 4% of the sickest Medicaid beneficiaries account for half of total program spending; 76% of the national Medicaid budget goes to acute hospital services, the most expensive setting of care. Palliative care services for patients with advanced illness improves quality of care, helps patients live longer and costs less.<sup>2</sup>

### Public Health Law Perspective: Rights to Palliative Care in New York

In New York State, unlike virtually every other state, patients now have a clearly defined right to receive information and counseling regarding palliative care and to receive palliative care, pursuant to changes in public health laws effective in 2011, the Palliative Care Access

Act<sup>3</sup> and the Palliative Care Information Act.<sup>4</sup> These critically important laws were enacted to: (1) address lack of communication or effective and timely communication between health care practitioners and their patients about palliative care; (2) promote the necessary provision of palliative care to appropriate patients; and (3) improve population health.

The Palliative Care Information Act (PCIA), effective 2011, was enacted to enable patients to make informed treatment decisions during the final months of their lives. It requires that attending health care practitioners offer patients who are diagnosed with a terminal illness information and counseling regarding palliative care and end-of-life options appropriate to the patient. This includes, but is not limited to, the prognosis, risks and benefits of the various options, including hospice, as well as the patient's legal rights to comprehensive pain and symptom management at the end of life. Information and counseling shall be provided to a person with authority to make health care decisions for the patient if the patient lacks decision making capacity.

The Palliative Care Access Act (PCAA), effective September 2011, builds on the PCIA and requires that hospitals, nursing homes, home care agencies, special needs assisted living residences, and enhanced assisted living residences establish policies and procedures that provide access to information and counseling regarding options for palliative care appropriate to patients with advanced life-limiting conditions and illnesses. These providers and residences must also facilitate access to appropriate palliative care consultation and services, including associated pain management consultation and services, and referrals consistent with patient or resident needs and preferences. Like the PCIA, when the patient or resident lacks capacity to make medical decisions, the information and counseling shall be provided to persons who are legally authorized to make medical decisions on behalf of such patients or residents.

The New York State Department of Health in its December 2011 letter to CEOs and Administrators made clear that the intention of these laws was, in part, for patients to be, "fully informed of the options available to them when they are faced with a serious illness or condition, so that they are empowered to make choices consistent with their goals of care, and wishes and beliefs, and to optimize their quality of life." At the same time, the laws were intended not to discourage conversations about palliative care with patients who have distressing symptoms and serious conditions, but do not fall within the strict parameters of the law. Palliative care can be provided simultaneously with disease-modifying therapies or life-prolonging care.

Implementation of these new laws will be difficult for a variety of reasons that create barriers. Many physicians do not even know what palliative care is and when it is appropriate. A study conducted for the Center to Advance Palliative Care in 2011 found that, “Physicians tend to either equate palliative care with ‘hospice’ or ‘end of life’ care and they are very resistant to believing otherwise.”<sup>5</sup>

Historically, health care professionals have not been well trained in palliative care and particularly management of pain, the most prevalent symptom which causes suffering. Consequently, they are not well-equipped to have conversations with their patients about palliative care, or to provide such care. As a 2011 Institute of Medicine Report stated regarding physician education: “The widespread prevalence of pain...demonstrates the need for medical educators to recognize it as a common and often severe condition. Yet there are strong indications that pain receives insufficient attention in virtually all phases of medical education—the lengthy continuum that includes medical school (undergraduate medical education), residency programs (graduate medical education), and courses taken by practicing physicians (continuing medical education [CME]).”<sup>6</sup>

With regard to providing pain care, the Institute of Medicine report noted that, “Although opioid analgesics are often indicated for chronic severe pain, people with such pain and institutions...can have difficulty obtaining them for various reasons. Sometimes it is a clinician’s reluctance to prescribe....”<sup>7</sup> The report also commented on the difficulty patients have in obtaining opioids due to pressure on physicians resulting from state and federal laws on drug abuse prevention which can impede effective pain management.<sup>8</sup>

Consistent with these recent findings, a 2005 Medical Society of the State of New York survey found that three-quarters of the doctors surveyed who prescribed a controlled opioid drug to an outpatient with chronic pain either occasionally or frequently prescribed a drug other than an opioid drug even when the opioid drug may otherwise be indicated. And, it also found that one third of those surveyed prescribed a lower dose occasionally or frequently because of concern about investigation by a regulatory agency.<sup>9</sup>

Although hospice is widely regarded as very beneficial interdisciplinary end-of-life care for the vast majority of people who are enrolled, in New York State the percentage of those dying with hospice care is far less than the national average. Moreover, in 2008, the last date for which statistics are available, about one third of those who died in hospice spent 8 days or less and another one third spent 31 days or less in hospice before they died.<sup>10</sup>

This evidence suggests that hospice referrals are not being made on a timely basis.

### Recommendations to Foster Effective Compliance with New Public Health Laws and Improve Public Health

Health care attorneys working with patients, health care professionals, and those who have affiliations with institutions where the PCIA and PCAA are applicable, should assist in appropriate ways to ensure compliance with these new public health laws. This might include informing seriously or terminally ill patients about their rights under these laws, working with facility staff and administrators on implementation, and conducting or seeking out those who will provide training on these laws.

Medical, nursing, social work, chaplaincy, pharmacy and other relevant schools should develop strong curricula or enhance existing curricula focusing on pain management, palliative care, end-of-life care, communication skills and advance care planning.

Legislation should be enacted which requires continuing education for health care professionals on pain management, palliative care, end of life care, communication skills and advance care planning. A recent study from California demonstrates the value of required continuing education on pain management.<sup>11</sup> Legislation should also be enacted which protects health care practitioners from professional discipline or criminal liability when ordering, prescribing, administering or dispensing pain-relieving medications or other treatments when practicing within the practitioners’ lawful scope of practice and in accordance with the reasonable standard of care.

At the state health department level, there are concrete steps that can be taken in working with public health professionals and advocates, including those in the legal system, to support public health initiatives that will improve public health. For example, in New York, dialogues between New York State Department of Health officials and leading public health lawyers and practicing professionals about implementation of the new palliative care laws have focused on amending the Patients’ Bill of Rights and the New York State Department of Health booklet, “Deciding About Health Care: A Guide for Patients and Families,” to include the rights that patients now have under the PCAA and PCIA. Important discussions have also been initiated about outreach to all the health professions including social work, and in particular making explicit in the department’s written guidance the social work profession’s vital role that in providing information and counseling on palliative care.<sup>12</sup>



## Public Health Policy and Ethics: National Palliative Care Movement

Public health law policies such as the initiatives taken in New York in promoting palliative care help to drive the translation of research evidence into appropriate legal and ethical practices. A constellation of factors calls for evidence-based palliative care interventions.<sup>13</sup> These factors include: (1) the aging demographic, (2) the prevalence of untreated and undertreated pain and symptoms of seriously ill older adults,<sup>14,15</sup> (3) the overuse of health technology and aggressive curative interventions that have marginal or no benefits for seriously ill individuals suffering from multiple chronic conditions, (4) escalating health costs that create inefficiencies in the delivery of health care, inequities in the allocation of resources, and growing health disparities among racial/ethnic minority groups,<sup>16,17,18</sup> and (5) varying levels of discomfort and distrust in the health care system.<sup>19</sup>

Palliative care interventions will need to target change at individual (e.g., seriously ill individuals, their family members and practitioners), system (e.g., public health, health and social service, and legal systems), and environmental levels (e.g., social, cultural, and community contexts).<sup>20,21</sup> In the national palliative care movement that has gained momentum in the U.S. over the last two decades, the broad aims of education and training for health professionals are to integrate normative principles about decision making with scientific evidence about clinical outcomes and cost savings. The implementation of palliative care interventions at multiple system levels will equip health professionals with enhanced knowledge, skills competencies, and values awareness to work more effectively with populations that have been underserved.

Target populations for palliative care interventions are seriously ill individuals who need information and counseling about their palliative and end-of-life options and may not be connected with a primary care practitioner such as isolated frail older adults. Palliative care interventions also seek to increase the number of minority adults with access to primary and palliative care services and satisfaction with services which are linked to better health outcomes and cost savings.<sup>22</sup> Such strategies aimed at reducing inequities in accessing palliative care services and eliminating health disparities among seriously ill individuals will improve public health and also help to address public health ethical concerns about equitable access to care and just allocation of scarce resources.<sup>23</sup>

## Conclusion

Essential to achieving the policy goals of better health and health care while reducing cost is building a generalist-level palliative care workforce to address unmet public health needs. Generalist-level palliative health care workforce development, formulation and implementation of new palliative care laws and policies, and translation and dissemination of interventions (practices, information, and counseling) into clinical practice are critical to effectuating multi-level change in the health systems that is supported by the best medical and social science evidence. Attorneys involved in public health law, policy and research will continue to play an important role in the creation and sustainability of new strategies and directions in palliative care that will achieve the three goals of better care, better health, and cost savings.

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## HEALTH LAW SECTION

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# Innovative Housing Solutions for Underserved Segments of the New York City Homeless Population

By Colleen Jackson and Autumn Hurst

Often there are subsets of the general homeless population who are underserved and seemingly overlooked. Many nonprofit providers shy away from targeting services to these special needs populations, generally citing lack of available funding as the major reason. However, using creativity and persistence, West End Intergenerational Residence HDfC, Inc. has obtained necessary funding and support to develop unique and innovative models that provide housing and services to these vulnerable, too often overlooked populations. West End prides itself on being a trailblazing housing and service provider.

West End's Intergenerational Residence is the only program funded by the New York City Department of Homeless Services that specifically serves the youngest heads of household in the shelter system and the only intergenerational program of its kind in New York State. The organization's recently opened True Colors Residence is New York's first and only permanent, affordable housing residence with on-site support services specifically serving LGBT youth with a history of homelessness.

## Housing and Services

### The Intergenerational Residence

Since its founding in 1989, West End Intergenerational Residence (WIR) has operated under one roof both a homeless shelter with social and educational services for young mothers and their children, as well as permanent affordable housing with on-site social services for low-income and formerly homeless senior citizens. Both populations occupy single rooms with kitchenettes. Although some units have private baths, most residents share communal bathrooms. Three of the ten residential floors are designated solely for seniors while the other seven floors are mixed.

### Transitional Housing for Homeless Young Mothers and Children

WIR provides 54 units of transitional housing paired with comprehensive, flexible social services for homeless, single mothers aged 18 to 24, each with one or two small children. Homeless families are referred to WIR through the New York City Department of Homeless Services (DHS) Family Shelter System. These families are then able to spend significant time receiving supportive services at the residence before placement in permanent housing. Those served come from all five boroughs of the city.

Though WIR's target population is broadly representative of the national population of homeless families, it

remains the only DHS-funded program specifically serving these very young families. These families experience high levels of traumatic stress. Figures provided by the National Center on Family Homelessness show that the vast majority of homeless mothers have suffered severe physical or sexual assault in their lifetime—from family members or their partners—and close to half lived outside their homes at some point during their childhood, with a sizable percentage having been in foster care. More than a third have experienced Post Traumatic Stress Disorder and over 40% were sexually molested as children. It is estimated that nearly half of homeless mothers suffer from depression and two-fifths from alcohol and drug abuse.<sup>1</sup>

Recognizing the social, physical, educational, and emotional development needs of parenting youth who have also undergone the trauma of family homelessness, it is West End's philosophy that it is more beneficial for them to be placed in a service-enriched environment that provides a reasonable, flexible length of stay. Many homeless youth require a longer length of stay in order to acquire the necessary skills and support they need to live independently, provide for their family, and avoid recurrent homelessness. While many homeless services programs in New York City operate with the goal of moving families into permanent housing as quickly as possible, West End recognizes that housing readiness is not one-size-fits-all. The homeless mothers served at WIR are the youngest heads of household in the shelter system. In addition to suffering the trauma of homelessness, roughly two-thirds of these women are also survivors of domestic violence. Youth who have no functional family supports, no employment experience, few educational opportunities, no budgeting skills, child care concerns, and who have never lived on their own before are at extreme risk of shelter recidivism.

WIR provides these women more than just temporary shelter. During their stay at WIR, young mothers are able to receive comprehensive educational, vocational, life skills, and child care services. The goal is to help women become self-sufficient by giving them the tools and support they need to continue their education, find employment, live independently, and break the cycle of violence for themselves and their children. All clients are encouraged to personally take part in assessing their own needs, developing individualized independent living service plans, and determining the specific services they are to receive.



For the children, on-site childcare not only provides a safe, happy learning environment but also allows their mothers to participate in programming, work, and find permanent housing. Almost a quarter of the homeless children served by West End have witnessed acts of violence within their family and nearly two-thirds have been exposed to violence. These homeless children suffer from emotional or behavioral problems that interfere with learning at almost three times the rate of other children.<sup>2</sup> WIR's Early Child Care Program addresses these issues with sensitivity and expertise and works in conjunction with the parenting skills workshops to help mothers nurture and more effectively care for their children, ensuring a physically and emotionally secure environment for each child.

The health needs of mothers and children are met through a relationship with the William F. Ryan Community Health Center, which runs an onsite clinic and provides health workshops three days a week.

Although every young mother arriving at WIR must concentrate on finding permanent housing, the organization's mission is to use the time it has with each client to help prepare them with the tools they need to make their futures more promising, both as parents and as contributing members of society. The programming created by West End for homeless young women with children encompasses a comprehensive case management effort built around services addressing the following:

- **Immediate Needs:** Crisis intervention; psychological support; coordination of referral services for health, substance abuse, and mental health needs; and other services designed to foster safety, recovery and self-sufficiency; also, advocacy for appropriate entitlements;
- **Transitional Services:** Assistance with job training and placement; legal services; housing assistance; counseling; and child care;
- **Individual Counseling:** Structured one-on-one counseling designed to facilitate healing, empowerment and client movement towards independence;
- **Peer Group Counseling:** Support groups to facilitate empowerment and independence;
- **Household Establishment Assistance:** Education to promote self-sufficiency and create an independent household, including instruction in nutritional meal planning, purchasing, and preparation; household budgeting; scheduling of child care, transportation, doctors appointments, counseling, etc.;
- **Independent Living Skills:** One-on-one and group education to strengthen family functioning, in-

cluding exercises to develop healthy interpersonal relationships and personal coping skills;

- **Parenting Skills:** Structured, customized education designed to strengthen healthy parenting practices including reversing the cycle of submission, fostering relevant understanding of child development, appropriate/effective discipline practices, promoting parental participation in the education of their children and developing self-esteem in themselves and their children;
- **Employment Counseling and Skills Training:** Aimed at developing and strengthening employment skills, preparing clients to work towards independence from public assistance programs and long-term self-sufficiency. Specifically, this programming provides comprehensive job skills assessment; referrals to job training and job placement services; and follow-up with clients and employers.

Until very recently, WIR was home to a successful on-site GED program provided through the NYC Department of Education (DOE). This program was eliminated in 2011 as a result of budget cuts within the DOE. West End, however, continues to promote education as the best means to true self-sufficiency. WIR continues to provide educational workshops and clients are encouraged, when able, to attend nearby GED courses. With encouragement some residents even enroll in college and are provided with as much support as possible to help maintain their studies.

WIR sponsors a Women's Empowerment Program, run by an in-house clinical social worker, to better serve the young families in its care. The Women's Empowerment Program serves as a cornerstone of WIR's efforts to help young mothers achieve true independence as they recover from incidents of domestic violence that may have contributed to their homelessness. A continuum of services was designed to intervene in the destructive cycle of force, fear, and violence that these young mothers and children have experienced. WIR's clinical social worker provides:

- Thorough assessment and psycho-social evaluation for every newly admitted family, including determination of any mental health or substance abuse issues;
- The emotional support necessary to break the bonds of an abusive relationship, including help for children to recover from the traumatic experience of the violence, and individual and group therapeutic counseling;

- Information and referrals to families displaced as a result of domestic violence, enabling them to secure needed outside supportive services, such as getting orders of protection;
- Encouragement to improve job skills and employability through education and training referrals and onsite supportive services.

Each year the comprehensive, flexible services provided at WIR give hundreds of young mothers and their children a chance to stop the cycle of homelessness and secure the skills and resources necessary to obtain and maintain true independent living.

### Permanent Supportive Housing for Formerly Homeless Older Adults

In addition to temporary services for young homeless families WIR provides permanent, supportive housing for 40 low-income older adults, aged 55 years and up. Older residents, like the young families, are homeless when referred to WIR by DHS. Referrals come from all five boroughs of New York City and the average age of residents is around 75 years.

In general, these are seniors who have not been able to manage on their own as a result of escalating rent, unemployment, physical and mental problems, and alcohol and drug abuse, all of which have contributed to their homelessness. The overwhelming majority of residents have spent some significant period of time homeless and almost none have any family or other support systems to help them beyond WIR's Staff Gerontologist, Program Case Manager, and the fellow members of the West End community. At WIR, these vulnerable older adults have found a welcoming and stable permanent home, with a room of their own and the on-site services they need to remain healthy and independent.

Many older adults come to WIR after a period of homelessness stemming from issues relating to substance abuse (particularly alcoholism) and mental health problems. Considerable staff time is spent giving these senior residents as much assistance as they need in obtaining appropriate referrals for treatment to agencies like St. Luke's-Roosevelt Hospital Center's Addiction Institute, as well as for needed entitlements and benefits. The first goal is ensuring that the basic health and welfare needs of each resident are provided for as best as available resources allow.

Through counseling and other means, social work staff helps clients cope with the unavoidable life changes and issues which accompany advancing age. These may involve securing legal advice for advance planning for incapacitation and final disposition. Assistance is also provided in designating health care proxies, establishing

burial accounts, or making arrangements to move to a long-term care facility.

On-site programming and services provided directly by WIR staff (or via community linkages) include:

- Intergenerational ceramics classes held once-a-week in the evening throughout the year (excepting the summer months);
- Communal birthday parties which serve to get residents out of their rooms and socializing with one another, as well as ensuring they get a nutritious meal at a time of the month when many have exhausted their entitlement checks;
- Cultural activities ranging from an in-house "Senior Movie Night" to regular trips to Broadway using Theater Development Fund half-price tickets;
- Field trips on the Circle Line around Manhattan, to the beach in the summertime, and elsewhere throughout the year;
- Annual Thanksgiving packages and Holiday gifts, which are usually arranged through drives at area schools and delivered to residents by local students and their parents;
- A regular slate of lectures and workshops in such areas as proper nutrition and preventive health for the elderly;
- A Foster Grandparent Program through the New York City Department for the Aging which helps get seniors involved in WIR's Child Care Program and also pays them a small stipend;
- The maintenance and provision of funds (through fundraising and private donations) for emergency and other unforeseen needs, which can include such things as helping with moving-in expenses, purchasing food when the resident has no other options, and, in rare circumstances, even helping to pay for burial expenses.

The William F. Ryan Community Health Center provides on-site services to WIR's older adults including health screenings, advice, and comprehensive care referrals as necessary. The Ryan Center also provides health care speakers who address issues such as nutrition and preventive care and emphasizes educating seniors about aging-related issues, so they may be well-informed to make their own decisions about health care and their future well-being. Roughly 80% of WIR's senior residents have diabetes and as a result of their histories of homelessness and abuse are aging more quickly than the general senior population. They also tend to have a far greater incidence of ailments such as emphysema and

asthma. Almost all take advantage of the easy availability of this clinic.

## True Colors Residence

True Colors Residence (TCR) is the first truly permanent housing program to specifically address the growing crisis of homelessness among LGBT youth. This profoundly underserved population is estimated to make up nearly 40% of all homeless and runaway youth;<sup>3</sup> however, services targeted to this population remain scarce. A number of LGBT youth who come out to their families are met with rejection and disapproval and an alarming number report being told by their families to leave home.<sup>4</sup> LGBT youth are often ostracized in school and other group settings solely because of their identity. They also face a greater chance of violent assault based on their sexual orientation and/or gender identity. Homeless LGBT youth experience a high level of harassment and violence on the street, in the shelter system, and elsewhere. They are further broadly affected by critically disabling problems such as substance abuse that is a primary barrier to independent living, mental illness, and risky sexual behavior. Prone to depression and generalized anxiety disorders, it is a population with a much-higher-than-average suicide rate. Further, although some youth have aged out of foster care or transitional living programs, most have not experienced an environment that provides a sense of community and helps them develop a network of support.<sup>5</sup>

True Colors Residence provides formerly homeless LGBT individuals aged 18-24, upon admission, a safe, stable, and supportive environment in which they can rebuild their lives. TCR houses 30 newly constructed and fully furnished studio apartments for residents, each with its own private bathroom and kitchen and generous closet and other storage space. Each resident holds a lease for his or her apartment and is responsible for paying affordable rent based on his or her income. All residents have access to both indoor and outdoor community space, a small library and computer room, and laundry facilities.

At TCR homeless, high-risk LGBT youth have access to much needed protection and assistance as well as the security of affordable housing with appropriate support services that meet the individual needs of tenants and enable them to live as independently as possible. Support efforts are aimed at assisting tenants to achieve and maintain physical and emotional health, stable and legal employment, safe housing, and consistent, reciprocal support from people who care about them.

Because of their age and possible trauma, it is unlikely that this population would on their own seek the above services at multiple locations. The ability to meet with social service and life skills staff on-site allows for a

greater chance of success in later years when they move on to housing without services. Tenants receive case management and ongoing assistance with every aspect of independent living. Comprehensive services tailored to each individual include:

- Benefits and entitlement advocacy;
- Health and education counseling;
- Job readiness and placement assistance;
- Independent living skills such as cooking, money management, and health issues, etc.;
- A range of additional services, including GED classes and health care, available through linkages with other nonprofit agencies.

Tenants directly participate in ongoing program implementation and management through regular community meetings and advisory boards. Participating youths are included in all aspects of program development and evaluation, including continual refinement of all services provided. TCR's Resident Council meets monthly with the Program Director and other key staff to provide feedback on current program activities and helps resolve issues that may have arisen. The Resident Council is designed to function as a forum for any youth to advise and consult with agency leadership.

Program staff members collaborate with each tenant to develop and update an individualized, flexible housing and support services plan that is designed to support the tenant in maintaining his or her housing, determine goals, and discuss outcomes. The on-site Life Skills Coach is responsible for developing and facilitating job readiness workshops along with acting as liaison with vocational resources, educational resources, and potential employment resources. Each tenant is assisted in accessing services and resources that will enhance his or her ability to secure gainful employment, including educational opportunities, job readiness skills and vocational training, and assistance with employment placement and retention. Additionally, there is a collaborative relationship with the Hetrick-Martin Institute, which specializes in providing a wide range of direct services, including education and referrals for lesbian, gay, bisexual, transgender, and questioning youth, and their families.

In operating TCR, West End chose to adopt a harm reduction approach that emphasizes tenant choice in the delivery of services and in which tenants' engagement in services and maintenance of sobriety (when relevant) is supported but not required. This harm reduction model allows each youth's experience to drive individualized assessment and service processes including the frequency, type, and scope of support offered. All plans address tenant access to preventive, ongoing, and emergency



services. Emphasizing open communication and trust-building between staff and tenants, substance use is detected primarily through observation or self-reporting and addressed through case management. In addition, program staff is informed about and sensitive to trauma-related issues present in tenants who may have histories of sexual or physical abuse or other trauma. Staff strives to deliver services in a way that will avoid inadvertent re-traumatization.

Each tenant is offered services to comprehensively address his or her physical and mental health needs including primary medical, mental health and dental care, HIV/STD prevention, treatment and support services (including access to condoms and rapid HIV testing), health and nutritional counseling/education, and any other appropriate services. On-site, a Licensed Clinical Social Worker provides psycho-therapeutic services, making referrals when more intensive services are necessary (such as when medication is indicated).

In addition to the mental health services provided by staff, regular on-site physical and mental health services are provided by the William F. Ryan Community Health Center's SHOUT (Special Health Outreach to Urban Teens) medical van. The SHOUT Van Program provides primary medical care and makes referrals to Ryan's Dental Department, Specialty Clinics including mental health services, and to Ryan's back-up hospital as needed. Tenants are also referred to other service providers based on preference and need.

### Development and Funding

West End Intergenerational Residence HDHC, Inc., was incorporated in 1987 and in the next year purchased the Congressional Hotel at 483 West End Avenue in New York City, a Single Room Occupancy facility which at that time had 27 mostly older residents.

A resource group was formed in consultation with the New York Foundling Hospital, Fordham University, Phipps Houses, and the Housing Development Institute of Catholic Charities of the Archdiocese of New York to help guide the effort to convert the hotel into a transitional residence for homeless young women and children, while also providing permanent housing for low-income and formerly homeless seniors.

The building was purchased and renovated through a mortgage loan of \$7,125,000 from the New York City Department of Housing Preservation and Development's (HPD) SRO loan program and the New York State Homeless and Housing Assistance Program. Upon the completion of major renovations in November 1989, the residence opened its doors and began operations. Eighty-five percent of its operating budget was funded originally by the New York City Human Resources Administration,

and today is funded by the DHS. SRO tenant rents and rental subsidies make up the other 15 percent.

From the onset a number of challenges presented themselves. Commonly held beliefs among non-profit providers popularized the notion of intergenerational conflict and proved to be an early challenge to West End's mission.<sup>6</sup> West End's founders, however, saw a different side, noting that both the elderly and young, single mothers share a number of needs including conveniently located public transportation, affordable supermarket and drug store shopping, and health care facilities. Further, both populations have a great need for reliable support systems.

Introducing intergenerational programming, of course, was not easy. While a number of former tenants accepted the project and signed leases in the building, all chose to live separate from the families on designated senior citizen floors. New residents, many specifically recruited for their interest in living in mixed-age housing, filled the apartments on intergenerational floors and began developing significant and meaningful connections with the families. Some older adults even began volunteering in WIR's Child Care Program. Today, a number of intergenerational programming opportunities including art workshops, field trips, and the Women's Empowerment Program continue to successfully forge connections across generations.

A second challenge lay in the proposed location of the residence. West End's founders faced a great deal of opposition from the traditionally high-income residents of Manhattan's Upper West Side who believed that housing for low-income and homeless individuals and families would be an undesirable addition to the neighborhood. Founders, however, remained undeterred, holding informational meetings for opponents and even taking the time to personally respond to calls and letters. Eventually, community members accepted the project, and although it was not required to continue with the building process, the Community Planning Board granted WIR unanimous approval. Further, community members volunteered to serve on a Neighborhood Advisory Committee as well as West End's Board of Directors, working with West End's leadership to find effective solutions for neighborhood concerns.

The challenges did not end in the development stages. Over the years West End has been encouraged by the City to compromise its mission, programs, and integrity as a service provider in order to comply with policies of various mayoral administrations. At one point, DHS required all family shelter providers to do away with population restrictions or risk budget penalties. WIR remained the only family shelter which chose to continue to serve its target population. West End's contract with DHS was

reduced as a penalty. Recent policy changes have placed enormous pressure on shelter providers to de-emphasize education and individualized services and place all heads of households into jobs and housing as quickly as possible. West End continues to maintain that self-sufficiency and housing readiness is not one-size-fits-all and that adolescent mothers require time to learn skills that will help them remain independent and permanently housed when they leave WIR.

Much like the development process of WIR, development of TCR was not without a number of challenges. The True Colors Residence was developed with capital funding from the New York City Department of Housing Preservation and Development (HPD) under the New York/New York III agreement. This 2005 agreement, which upon its introduction was the largest commitment to creating housing for homeless people in the nation, committed to creating 9,000 units of supportive housing for a variety of vulnerable, special needs populations in New York City. Support services at TCR are provided through a contract with New York City's Department of Health and Mental Hygiene.

In order to obtain capital funding from HPD, a letter of recommendation from the local community board or other elected official was required. In this case, however, the community board had passed a moratorium on supportive housing, claiming the community was oversaturated with such programs. Refusing to give up, West End investigated further and learned that there was a misunderstanding about supportive housing. Community board members believed it to be a definition for drug rehab and treatment programs. Despite West End's best efforts to dispel this notion, the community board remained fearful and evasive and the District City Council Representative refused to recommend support for TCR without the approval of the community board. After a year of attempts to engage the community board, West End obtained a letter of support from the Manhattan Borough President to satisfy HPD requirements, and began construction. Today, it should be noted, True Colors Residence enjoys the support and praise of the community and all of the elected officials of the district.

Another challenge was West End's commitment to keeping the project small so that residents would feel an atmosphere of community and peer and staff support. Citing economies of scale, HPD pushed for a 60-unit project; West End, however, would agree to no more than 30 units. Ultimately HPD agreed to the size, though one more problem quickly arose: the project was being developed at the height of an economic recession. The low value of tax credits necessary to finance the equity of the project, combined with the fact that West End had not developed any projects since the 1980s, made locat-

ing an investor for the Low Income Housing Tax Credit Program difficult. West End was ultimately successful; however, despite financing from HPD and tax credit investors, it was still necessary to seek additional funding to fill budget gaps. Remaining committed to the project, West End eventually cobbled the True Colors Residence's total development funding of roughly \$11 million together from a variety of sources. Citi Community Capital provided nearly \$6 million in construction loan and permanent equity funds, including the purchase of \$3.384 million in Low-Income Housing Tax Credits (LIHTCs). HPD's Supportive Housing Loan Program provided \$3.78 million in construction and permanent lending through HOME funds. Contributions also include \$2.79 million in federal Tax Credit Assistance Program funds; a \$500,000 grant from Manhattan Borough President Scott Stringer; \$465,000 in construction and permanent lending from the Federal Home Loan Bank's Affordable Housing Program through member M&T Bank; and a \$75,000 grant from New York State Energy Research and Development Authority (NYSERDA). The LIHTC equity was syndicated by Richman Housing Resources. Acquisition and pre-development financing for True Colors Residence was provided by the Corporation for Supportive Housing and the New York City Acquisition Fund.

These myriad challenges, however daunting, have paved the way for West End's success and growth. Today, WIR has served more than 2,600 young families and over 90 older adults, all under one Upper West Side roof. West End has extended its organizational capacity to include building management and counseling and program services at two facilities in the Hamilton Heights and East Harlem neighborhoods of Manhattan. Further, the True Colors Residence now provides a safe, supportive home with flexible support services to 30 formerly homeless LGBT young adults, many of whom are holding a lease for the very first time.

### Vision

For more than twenty years, West End's mission has been to provide safe and supportive transitional and permanent housing together with comprehensive services that assist and empower homeless and formerly homeless youth, families, and older adults to live full and productive lives. Its long-running programs continue to successfully serve hundreds of vulnerable individuals and families each year. This organization has developed innovative and one-of-a-kind programs, creating a dedicated, unique and growing community in which the neediest New Yorkers are able to get a new start in life. As new challenges arise, West End continues to carry out its mission by taking the lead in advancing creative solutions to address the needs of New York City's most underserved populations.

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**for 21 years, the last 15 as Executive Director. A tireless advocate for the homeless, Ms. Jackson served as President of Homeless Services United, a coalition of New York City shelter providers, for five years and continues to work with government and elected officials toward improving policies and services for the City's most vulnerable citizens.**

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*Shortly after this article was written, West End announced an organizational name change. West End Intergenerational Residence HDFC, Inc. is now West End Residences HDFC, Inc., a shift which more accurately reflects all current and future services and sites of the organization. They can be found on the web at [www.westendres.org](http://www.westendres.org).*

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PUB1046



# Aging Prisoners: A National and International Public Health Crisis—Human Rights Concerns, Legal Challenges and Policy Reforms

By Mary Beth Morrissey and Tina Maschi

## Introduction

Aging prisoners are a largely overlooked population whose health and well-being needs have raised serious human rights concerns across the globe. The unmet needs of aging prisoners constitute a full-blown public health crisis that has ethical implications for the nation, the world, and for attorneys and other interdisciplinary professionals practicing in the health and public health fields or involved with policy decision making and reform. A substantial body of evidence points to serious threats to the health and well-being of older adults in prison, particularly related to their physical, mental health and safety needs, resulting in part from excessively punitive national policies and laws.<sup>1</sup> This article outlines the issues that are common to both the global and U.S. public health crisis in understanding and fashioning appropriate public health policy and ethical responses to the needs of aging prisoners.

## I. Growth of Aging Prisoner Population

A portrait of the international prison population suggests a growing global crisis in public health. The World Health Organization (WHO) documents that there are over 10 million people worldwide living in penal institutions.<sup>2</sup> According to the National Institute of Corrections (NIC), the prison population may be classified as “older adult” or “elderly” beginning in their 50s as opposed to the traditional retirement age of 65, as the average prisoner has a reduced health status approximating the health condition of non-incarcerated people who are 10 to 15 years older.<sup>3</sup> Across the world, the number of adults aged 50 and older in prison varies and has been steadily increasing over the past two decades, especially in the United States and Canada.<sup>4</sup> Current global statistics reveal that of the roughly 2.3 million adults in custody in the United States, 12% (n = 186,700) are aged 50 and older.<sup>5</sup> In comparison to others countries, the U.S. has a higher number of prisoners age 50 and older compared to Canada (n=2,800), Australia (n = 1,472) and England (n = 6,417).<sup>6</sup> Global efforts are in place to address the aging prisoner crisis. The WHO Regional Office for Europe has recognized the seriousness of this crisis through the work of its Health in Prisons Project (HIPPP) which has had an active focus on prisoners’ health as integral to the public health since its establishment in 1995.<sup>7</sup> The 2010 Madrid Recommendation,<sup>8</sup> *Health protection in prisons as an essential part of public health*, called for improved pre-

ventive and protective health care in all prison systems, alternatives to imprisonment to reduce prison overcrowding, guaranteed care for prisoners upon entry and post-release, and widespread acceptance and dissemination of the Madrid Recommendation as a whole.

Advocacy efforts and public awareness campaigns are currently under way in the U.S. to address the aging prisoner crisis.<sup>9</sup> For example, the recently issued report by Human Rights Watch, *Old Behind Bars: The Aging Prison Population in the United States*,<sup>10</sup> provides the following data that underscore the seriousness of the crisis in regards to the rapid population growth and long sentence lengths in the older adult population in the nation’s prison systems:

- Between 2007 and 2010, as noted above, the number of sentenced state and federal prisoners age 65 or older increased by 63 percent, while the overall population of sentenced prisoners grew only 0.7 percent in the same period. There are now 26,200 prisoners age 65 or older.
- Between 1995 and 2010, the number of state and federal prisoners age 55 or older nearly quadrupled (increasing 282 percent), while the number of all prisoners grew by less than half (increasing 42 percent). There are now 124,400 prisoners age 55 or older.
- As of 2010, 8 percent of sentenced state and federal prisoners are age 55 or older, more than doubling from 3 percent in 1995.<sup>11</sup>

Stricter sentencing laws have resulted in many prisoners growing old and dying in prisons. In fact, the American Law Institute<sup>12</sup> reports that the decade of 2010-2019 may very well be the most punitive in the nation’s history based upon person-years-served.

According to Human Rights Watch:<sup>13</sup>

- One in ten state prisoners is serving a life sentence.
- Eleven percent of federal prisoners age 51 or older are serving sentences ranging from 30 years to life.<sup>14</sup>

Two major reasons have been identified as contributing to the global aging prison population crisis: an increase in the aging population coupled with the long-term aftermath of stricter sentencing policies instituted in the 1980s,

particularly in the U.S.<sup>15</sup> The conservative U.S. criminal justice policy shift that began in the 1980s was part of a broader policy turn to the ideology of neoliberalism, and resulted in stricter public and legislative policies such as the Rockefeller Drug Laws as well as Truth in Sentencing and Three Strikes You Are Out legislation.<sup>16</sup> This shift in ideology is reflected in the courts, giving adjudicated offenders longer mandatory prison sentences including an increase in the number of life sentences without parole. Currently, many countries, especially the United States, Canada, Australia, and England are grappling with being ill-prepared and equipped to address the health and safety needs of aging prisoners, many of whom who are in need of long term care.<sup>17</sup>

## II. Prisoners' Rights to Medical Care in the United States

Key decisions of the U.S. Supreme Court protect older adults in prison and their rights to medical care. In 1976, *Estelle v. Gamble*<sup>18</sup> established a constitutional right to health care that is guaranteed to prisoners in U.S. prison systems. For over thirty years, this right has generally been protected by the courts, and is recognized in the correctional health care literature.<sup>19</sup> More specifically, it is also well established that the right to health care under *Estelle* guarantees to prisoners three fundamental rights protected by the Eighth Amendment under a narrow standard adopted by the courts of "deliberate indifference to serious medical needs"—rights of access to health care, rights to receive care ordered by a medical professional, and rights to a professional judgment made by a medical professional.<sup>20</sup>

Even in light of these constitutional protections, the seriousness of medical and mental health problems among prisoners continues to be a major concern and the subject of multiple class action suits. In May 2011, the United States Supreme Court in *Brown v. Plata*<sup>21</sup> upheld a lower federal court ruling that found egregious violations of prisoners' constitutional rights to medical and mental health treatment in California prisons due to ongoing severe overcrowding. The release of over 40,000 prisoners was ordered by the Court.<sup>22</sup> This decision and order of the Supreme Court resulted from the consolidation of two class action suits on behalf of prisoners with serious medical conditions and mental disorders and ongoing violations of the Cruel and Unusual Punishments Clause of the U.S. Constitution over a period of years. These ongoing violations escalated the number of suicides among the prisoners to nearly one a week, a rate that was 80% higher than the national average.

## III. A Global Portrait of Aging Prisoners

Older adults in the criminal justice system have complex physical and mental health, housing, financial, legal and social needs, especially when poised for com-

munity reintegration.<sup>23</sup> In its 2012 report, Human Rights Watch<sup>24</sup> provides the following snapshot of the everyday struggles of older adults in prison:

Prisons in the United States contain an ever growing number of aging men and women who cannot readily climb stairs, haul themselves to the top bunk, or walk long distances to meals or the pill line; whose old bones suffer from thin mattresses and winter's cold; who need wheelchairs, walkers, canes, portable oxygen, and hearing aids; who cannot get dressed, go to the bathroom, or bathe without help; and who are incontinent, forgetful, suffering chronic illnesses, extremely ill, and dying.<sup>25</sup>

The report states further that based upon research and visits to prisons, there is evidence of violations of aging prisoners' human rights.

In addition to conditions of confinement, community reintegration of older adult prisoners is rapidly becoming of significant concern in countries across the globe. For example, in the United States, roughly 600,000 prisoners are released back to the community, every year.<sup>26</sup> In the U.S. over the course of a decade (between 1990 and 1999), older adults released to the community increased from 5,000 to 9,000, every year.<sup>27</sup> Therefore, it is critical that communities across the world are better prepared to assist older adults with varying prison sentence lengths.

## IV. Age Group Comparisons

Older adults compared to juveniles and adults have similar yet unique developmental needs that distinguish them from different age groups of prisoners. These are important considerations for the legal community when working with older adults involved in the criminal justice system. In prison, younger and older adults have common experiences of social exclusion: the need for social contact and to engage in meaningful activities. For both "new" prisoners (both young and older), there is prison "entry" shock, institutional adjustment, and "psychological survival" process.<sup>28</sup> They also have histories of traumatic and stressful life experiences (e.g., being a victim of physical and sexual abuse age 16 and younger).<sup>29</sup>

## V. Differences and Challenges of Older Adults in Correctional Settings

**A. Cost differences.** There are significant cost disparities to house older adults compared to younger prisoners. For example, in the United States, it costs approximately \$70,000 a year to house an older adult in prison, which is over three times the cost of housing a younger prisoner (\$22,000).<sup>30</sup> The major bio-psychosocial differences that contribute to these higher costs for older adults in

corrections are attributed to age-related health, mental health, criminal histories, prison victimization, mortality and stress, and history of traumatic and stressful life experience.

**B. Age-related health, mental health, and prior trauma.** As a natural part of the aging process, older adults in prison have higher rates of chronic illness or disability (e.g., health and lung disease, HIV/AIDS) compared to younger prisoners. For example, in the United States, most (68.5%) reported some type of chronic medical problem, such as arthritis (32.6%), hypertension (30.6%), tuberculosis (15.8%), and heart problems (13.3%),<sup>31</sup> which are health differences that increase with age.

Global statistics reveal a high prevalence of mental health issues among prison populations, including older adults. For example, U.S. national statistics reveal that 50% of prisoners aged 50 to 54 and 36% percent of prisoners aged 55 and older have mental health problems. Interestingly, only about one third will have access to treatment while in prison.<sup>32</sup>

A unique aspect for older adults is the natural process of aging and mental health, which often means cognitive decline, especially in the stressful prison environment. Poor health behaviors coupled with the prison environment place them at increased risk for age-related mental health problems, especially dementia, which is a cruel and unusual disease process that results in loss of physical and cognitive capacities and ultimately results in death.<sup>33</sup>

Evidence also suggests that older adults compared to younger adults in prison are more than likely to experience stress related to chronic losses (sudden and expected), or being diagnosed with a physical or mental illness.<sup>34</sup> They also report a higher degree of psychological distress related to the fear of dying in prison and victimization.<sup>35</sup> Death anxiety among older adults in prison has been commonly reported among older adults in prison.<sup>36</sup>

**C. Criminal histories.** Older adults are more likely to have histories of prior incarcerations and recidivism compared to younger prisoners. Older adults with serious offenses (especially when coupled with disabilities) are particularly hard to resettle back in the community post-prison release. Older adults are commonly noted as less likely to recidivate compared to younger adults.<sup>37</sup>

## VI. Prisons: Geriatric Health Care Services

Despite recognition of prisoners' human rights and constitutional guarantees to medical care, correctional systems are in many cases not prepared to provide minimally adequate services to aging prisoners. Currently, there is a lack of programming specific to older adults promoting the health and well-being of older adults in prison across the globe. Older adults in prison often do

not benefit from prison programming targeting younger prisoners' needs, such as reducing their offending behavior, education, vocational, and employment programs.<sup>38</sup> According to the 2000 U.S. Bureau of Justice Statistics Survey of Correctional Facilities, only 4% (n=38) of state correctional institutions provided any type of geriatric-specific health care services. One percent of state institutions offered services in geriatric care facilities, 2% had segregated geriatric units, and 1% had mixed (younger-older) unit models.<sup>39</sup> Palliative care and information and counseling about end-of-life options are needed in prison,<sup>40</sup> especially since over 3,000 U.S. prisoners a year may die in prison<sup>41</sup> and many older adult prisoners are chronically ill. Examples of promising practices that foster health and well-being of older adults in prison and the community are outlined below.

The literature suggests that older adults have a more difficult psychological adjustment to prison and community reintegration (prisoner reentry) than their younger counterparts. The reality of declining health often places older adults in a state of high alert to victimization and/or fear of dying in prison. Social well-being is an important concern for older adults in prison. Older adults also are more than likely to have elderly spouses and other family members that make the prison experience (and reentry process) more problematic.<sup>42</sup> Some scholars document "institutional thoughtlessness" of staff in the treatment of older prisoners.<sup>43</sup> In prisons, older adults often are less of a problem for staff, which may lead to their being neglected or forgotten. Staff may not provide older adults with supports, such as wheelchairs or assistance climbing stairs. Sometimes they assign volunteer prisoners the responsibility of caring for older adults without providing them with the proper training, which does not meet proper standards of care.<sup>44</sup>

## VII. Community Reintegration

An important consideration for attorneys and other interdisciplinary professionals to be cognizant of is that there are no constitutionally based rights to health care in the U.S. once older adults exit prison and enter the community as non-incarcerated adults. In the absence of any comprehensive long term care policy in the U.S., this population of older adults faces high dependency and care needs outside of prison with no health care warrant. For example, older adults are often more difficult to resettle in the community, especially when they have longer sentences that resulted in institutionalization (e.g., they don't know how to survive outside of prison).<sup>45</sup>

Resettlement success for older adults may be compounded by limited financial resources, health and/or mental health issues, lack of family and peer support, ongoing substance use, lack of available health, mental health, substance abuse community services, suitable



housing options or shelter services, and transportation. Some older adults are in need of Medicare and/or Medicaid or in need of retirement assistance. Even assistance with everyday practical issues, such as getting or replacing eyeglasses or hearing aids, taking care of one's personal hygiene and clothing is warranted. This process takes time, and if it is not started early enough in prison, older adults may enter the community without the proper services in place.<sup>46</sup> For able-bodied older adults, employment is another factor to consider to help foster successful community reintegration. In contrast, for older adults who have physical and/or mental disabilities, long term care is essential for access to community-based or institutional long term care.

An important consideration in the current global economic climate is the relationship between economic policy, economic trends, and social welfare policy. In a time of scant resources and stagnant economic growth, economic opportunities are limited. Therefore, older adults exiting prison based on their age and ex-offender status will have an increasingly more difficult time obtaining needed economic and employment opportunities, and are at an increased risk of homelessness.<sup>47</sup>

These complex issues faced by aging prisoners re-entering society suggest that in order for attorneys to be most effective in advocating for or representing this population, it is increasingly important to work collaboratively with interdisciplinary professionals to assure that their multidimensional physical health, mental health, social service and social support needs are met.

## VIII. Promising Public Health Solutions

There are some examples of existing programs that assist aging prisoners in accessing appropriate services to assess needs and assure adequate health and mental health care, personal safety, and housing. Although so few institutions offer essential geriatric-specific services, there are several innovative programs that focus on care issues such as dementia that foster older adults' health and well-being. Characteristics of these programs include one or more of the following: "age" and "cognitive capacity" sensitive environmental modifications, interdisciplinary staff and volunteers, and services specifically designed for older adults with dementia or cognitive impairment from early to late stages, including hospice care. However, the degree to which these promising programs is effective in their outcomes has yet to be fully determined.

### A. Innovative Prison Programming

1. **The True Grit Program.** The True Grit Program in Nevada is a structured living program that attempts to deal with the special needs and foster the well-being of the rapidly increasing popula-

tion of geriatric inmates. Together with Nevada's Division of Aging Services, the program was designed to enhance physical health (by means of various recreational and physical therapy activities); mental health (using group and individual therapy and self-help modalities); and spiritual health (coordinated with the prison chaplain and volunteers).<sup>48</sup>

2. **The Unit for the Cognitively Impaired (UCI; New York-America).** The UCI program in Fishkill, NY, is a specialized dementia unit and is known for its innovative design such as adequate lighting including windows, and access to an outdoor patio as well as its use of animal-assisted therapy to help with relaxation and relief of pain and suffering.
3. **Hospice/Mental Health-Prison Companion Programs-America.** Recent statistics suggest that there are over 70 hospice programs in prisons and more being developed that help foster dignity and respect among dying prisoners.<sup>49</sup> Projects such as Robert Wood Johnson's Grace Project (Guiding Responsible Action for Corrections at the End-of-Life) have been collaborators with corrections to enable individuals close to the end of their lives to die with dignity and respect. In comparison, the Angola Prison Hospice is a state prison hospice program. It is one of a growing number of hospice programs for dying inmates. Prisoners volunteer for the program and are taught basic hospice practices and how to counsel and provide assistance with activities of daily living.<sup>50</sup>
4. **Project for Older Prisoners.** The project that perhaps has been the most effective legal response to the aging prisoner crisis is the Project for Older Prisoners (POPS). A prison-to-community advocacy program in the United States, begun in 1987 at Tulane Law School, has expanded to multiple locations across the United States. Founded by Professor Jonathan Turley of the George Washington Law School (Washington, DC), the POPS program uses law students to advocate for older adults in prison who have non-serious offenses to obtain supervised parole.<sup>51</sup>

Law students assist individual low-risk prisoners over the age of 55 to help them obtain paroles, pardons, or alternative forms of incarceration. In a typical case, a student will prepare an extensive background report on a prisoner to determine the likelihood of recidivism. If the risk is low, the student will then locate housing and support for the prisoner and help prepare the case for a parole hearing. It also addresses the needs of the victim's families because offenders cannot be considered for release unless the victim's family agrees to it. The program

boasts a success rate of community placement and no known cases of recidivism among those released.<sup>52</sup>

## IX. Legal and Policy Reforms

Despite earlier gains in legal and policy reforms that directly affect aging prisoners, there is still much more that legal professionals can do to move forward legal and policy reforms. The \$60 billion in reentry costs to American taxpayers could likely be significantly reduced with the adoption of effective strategies for prison and reentry services, especially with older adults with diverse needs.<sup>53</sup> Proposed legal, policy and practice reform efforts should address older adults' cost containment issues while in prison, as well as the costs associated with their successful transition to the community. Older prisoners' physical, social and psychological needs are complex. This complexity creates the need for informed and targeted services and social support for older adults and their families and caregivers during any point of criminal justice contact from arrest, court, probation, prison, and parole.<sup>54</sup>

**A. Policy gaps.** Policy decision making in the U.S. that has failed to adequately address the urgent health and mental health care needs of older adults in prison heightens their pain and suffering experiences<sup>55</sup> and increases their risk for adverse health outcomes. These multiple policy failures have a disproportionate impact on minority older adults in the prison system and contribute to broader health disparities at the population level. It has been shown that older adults released from prison have lower recidivism rates than their younger counterparts, and are generally viewed as less of a public safety threat.<sup>56</sup> Cost shifting and cost saving rationales as well as human rights concerns have been the impetus for several states turning to discretionary parole policies, inmate furloughs, early release home detention programs or medical or compassionate release to relieve in part the aging prisoner crisis.<sup>57</sup> According to Chui,<sup>58</sup> the policy challenge, especially for attorneys, is to see that these policies and laws that are rarely used are implemented. Collaborations and pooled funding with public health departments, hospitals, and universities, and the development of a common database management system also hold promise to address gaps in services, especially for seriously ill older prisoners.<sup>59</sup>

**B. Policy responses and recommendations for system reform.** There are multiple public policy responses that need to be weighed and considered in addressing the complexities of this important public health problem. Several of them target education for prison staff and professionals who are providing services to prisoners, prisoners themselves, and their families and caregivers. These responses include: i) providing education to prisoners as early as possible in the course of their prison or

illness experience about their rights to make health care decisions, participate in shared decision making processes, engage in advance care planning and make advance directives, and exercise their constitutional right to refuse medical treatment, subject to certain limitations;<sup>60</sup> ii) providing professional education to prison staff and other professionals who are providing critical services to older adults in prison about shared informed medical decision making and promotion of health literacy, issues concerning decision making capacity for older adult prisoners and clinical assessment of capacity, and identification of legally authorized decision makers for incapable prisoners; and iii) providing education and social support to prisoners and their families and caregivers about person-centered care that will engage older adult prisoners in a process of making choices, fostering the constitution of personal agency or recovery of lost agency and improving their quality of life.<sup>61</sup>

Approaches to system reform are currently being examined at federal and state levels, and by policy experts and legislators. Jonathan Turley, Esq., highlighted the following recommendations in his 2007 Testimony on Prisoner Reform and Older Prisoners before the House Judiciary Committee: (1) the establishment of Project for Older Prisoner Programs (POPS) programs throughout law schools to identify and evaluate low-risk prisoners within the system for parole release; (2) the creation of a system for the supervised release of low-risk, high-cost prisoners; (3) the creation of alternative forms of incarceration for mid-risk prisoners to reduce costs; and (4) the establishment of geriatric units for high-risk, older prisoners.<sup>62</sup>

## X. Conclusion

As illustrated throughout this article, the global and U.S. aging prisoner populations represent one of the most overlooked human rights and social justice issues. Conditions of confinement in prison often compromise their health and well-being, and in many cases deny their constitutional right to health care. The literature suggests that most international prisons and communities are poorly equipped to address the complex recovery needs of older adults while in prison or post release. Essential human rights and social justice values, such as dignity and worth of the person, are commonly overlooked due to societal stigma and discrimination commonly associated with elderly and offender status. Moreover, older adults in prison are subject to medical neglect and physical and psychological victimization because of their increasing frailty due to age. Poor conditions of confinement also often have a significant toll on their physical and mental health status.<sup>63</sup>

At the turn of the twentieth century, we created a unique system for juveniles because it was the view that this age group had unique developmental needs.

Spearheaded by social workers, such as Jane Addams, a separate juvenile justice system was created to address juveniles' unique developmental needs.<sup>64</sup> In the early 21st century a similar argument can be made about the unique developmental needs of older adults in the criminal justice system and the establishment of an elder justice system. As suggested by the evidence reviewed in this article, older adults have unique developmental needs often based on a lifetime of cumulative disadvantage that distinguishes them from younger adults in the criminal justice system. Having a court system that can address the special needs of older adults is warranted. Attorneys engaged in health and public health law practice and research as well interdisciplinary professionals are encouraged to adopt interdisciplinary collaborative approaches that can help facilitate the advancement of global human rights, health and well-being for the aging prison population.

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# Does Health Care Reform Make Every Provider and Public Health Practitioner a Researcher?

## The Brave New World of Advancing Public Health Using Data in Research, Practice and Quality Control

By Karen L. Illuzzi Gallinari, Julia Goings-Perrot and Brian Currie

### Introduction

From the earliest discoveries of infection control through the current explosion of genetics, patient information has been used to find ways to prevent and control disease in individuals and populations. Public health authorities, health care providers and patient advocates have relied upon laws designed to enforce our commitment to the protection of human rights and the prevention of harm incident to the use of patient data. The nature of public health research, public health practice and performance improvement has made it challenging at times to determine which laws apply. Further, technology has advanced our ability to retrieve and utilize increasingly personal information. More data are being requested by government authorities to implement and test new approaches to health care delivery. These developments have led to additional privacy protections and refinement of existing laws to minimize risk to patients.

Providers at the interface between public health practice and public health research have managed to navigate the regulations controlling the use of patient data. To date, however, public health initiatives have been focused on minimal expectations of compliance with standards of care. The ability to study increasing amounts of valuable data and the need to raise the bar on health care performance require practical approaches to balancing the benefits of access to patient data with the risks of misuse.

National health reform initiatives are forcing the issue by requiring that providers be accountable for the health of their patients. They also reward providers willing to be financially invested in the success or failure of the advice and the care they provide. The exchange and analysis of patient data necessary to accomplish these goals are indeed giving each provider a role in the national effort to assess if this outcome-oriented approach will improve the quality of care provided to, and the health of, the people within our borders. Therefore, while many providers are not personally conducting research, each is, at the least, contributing to research and is playing a role in public health.

This article reviews patient privacy protections that have controlled the use of data for public health initiatives. It discusses the impact of health care reform and

pending rulemaking designed to increase our ability to maximize the value of the data available while staying true to our commitment to patient privacy. It also presents the provider's perspective on the realities that must be considered as we forge ahead in the brave new world of public health.

### I. The Use of Health Information to Improve Public Health

Public health is the science of protecting and improving the health of individuals and communities. Public health professionals analyze the effect on health of genetics, personal choice and the environment in order to develop programs that promote health. Community populations can be as small as a family unit or local neighborhood, and as big as entire countries and international communities.

Public health professionals aim to prevent illness from happening or re-occurring through implementing educational programs, developing policies, administering services, and regulating health systems and health professions. Public health is also the discipline concerned with limiting health disparities, by improving accessibility and health care equity. Every aspect of public health involves access to the study of health information about individuals and populations. The necessity for access to patient information for public health research and practice is evident from the earliest documented public health discoveries. Examples are discussed below in Section III, A Provider's Perspective.

Regulations relevant to the use and disclosure of patient information for public health research and practice start with those applicable to all medical research.

#### A. Public Health Research

Serious abuses of physician-patient trust in the name of research led to the enactment of patient protections codified in the *Common Rule*.<sup>1</sup> The Common Rule defines research as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."<sup>2</sup> It applies to research involving living human subjects or their identifiable private data.<sup>3</sup> It specifies informed consent

requirements and internal review board practices.<sup>4</sup> It also requires patient privacy protections.<sup>5</sup>

At some point in the genesis of the evaluation of a public health initiative the activity meets the broad definition of research. Nonetheless, the drafters of the Common Rule acknowledged that requiring patient consent was not practical or necessary by exempting activities using de-identified data from the definition of human subject research<sup>6</sup> or by waiving the consent requirement under certain circumstances.<sup>7</sup>

Legitimate concerns about the need to minimize privacy risk, given the vulnerability of electronic medical records, necessitated the enactment of HIPAA and similar state health information privacy laws.<sup>8</sup> HIPAA also contains permission for patient information to be used for research without specific patient consent when the data being used is sufficiently stripped of identifying information. Patients are informed of this through the Privacy Notice providers are required to give each patient.<sup>9</sup>

## B. Public Health Practice

The results of research instigated many of the public health protections we take for granted, including local sanitary codes, vaccination programs and infection control standards. The maintenance of public health is dependent upon regular monitoring and surveillance of health data. Mandates for providers to disclose the data required and the permission for them to do so are codified in state laws. Patient consent is not required when data are provided for public health practice.<sup>10</sup> For example, in New York, physicians are required to report every confirmed or suspected case of specific communicable diseases within 24 hours.<sup>11</sup> HIPAA also permits the use of patient data for “population-based activities relating to improving health or reducing health care costs.”<sup>12</sup>

States also recognize distinctions between public health practice and research. For example, New York State’s Public Health Statute for the Protection of Human Subjects exempts epidemiological investigations from the definition of human research.<sup>13</sup>

## C. Quality Control

While public health practice involves community-wide monitoring and surveillance, institutional quality assessment and improvement activities similarly require the use of patient health data. Industry wide quality improvement is also the mechanism by which governmental and voluntary health agencies implement health care improvements.<sup>14</sup> HIPAA also permits the use of patient data, without specific consent, for health care operations including quality control and other internal practice improvement efforts.

Specifically, patient consent is not required for “conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, (provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities); .... protocol development, case management and care coordination....”<sup>15</sup> Improving compliance with standards of care, and educational community outreach to increase vaccination initiatives are examples of quality control and performance improvement initiatives that usually fall within this permissible use of patient data.

In fact, the use of data for quality improvement is essential to responsible delivery of health care and necessary for advances in public health. As several experts articulated, “Quality improvement is a morally mandatory element of medical care, both for institutions to design... and patients to...embrace.”<sup>16</sup> Nonetheless, even within quality improvement activities some projects do constitute research warranting patient consent.<sup>17</sup>

## D. Other Privacy Protections

One of the more recently enacted patient data protections is the Genetic Information Nondiscrimination Act (GINA).<sup>18</sup> GINA prohibits employers from (1) intentionally acquiring genetic information about applicants or employees, or (2) from discharging, refusing to hire, or otherwise discriminating on the basis of genetic information. Employers who receive genetic information must keep it confidential and apart from other personnel information, in separate medical files.

## E. Resources Available Now

State and federal regulations applicable to permissible use of health information are found in various statutes and are implemented by multiple governmental agencies. Regulatory revisions, discussed below, have been proposed to streamline and simplify interrelated provisions. In the meantime, health care providers and public health officials can look to the following resources for guidance documents and the text of applicable laws.

### 1. U.S. Office of Health and Human Services

The U.S. Department of Health and Human Services is the government’s principal agency for protecting the health of Americans. It has several subordinate organizations which share responsibility for human subject research and public health practice. They include the following agencies, which provide educational material and provider guidelines to assist in compliance with applicable regulations.



### a. Center for Disease Control and Prevention (CDC)

#### i. CDC Guidance

The CDC prepared a number of guidance documents to assist health departments and institutions that conduct collaborative research in their efforts to distinguish public health research and public health practice. Its most recent publication on the issue is its policy for Distinguishing Public Health Research and Public Health Nonresearch.<sup>19</sup>

The CDC's HIPAA Privacy Rule and Public Health Guidance is similarly instructive for both public health practitioners and health care providers.<sup>20</sup>

#### ii. Public Health Information Network (PHIN)

CDC's PHIN is a national initiative to improve the capacity of public health partners to securely, effectively and efficiently exchange data. It aims to harmonize public health information exchange with the Nationwide Health Information Network.<sup>21</sup> Toward that end, PHIN provides a PHIN Certification to support the development and implementation of applications and information systems that comply with the PHIN Requirements.<sup>22</sup>

### a. U.S. Office of Human Research Protections

The U.S. Office of Human Research Protections (OHRP) is a division of the U.S. Department of Health and Human Services and is responsible for providing guidance on and enforcing the Common Rule with respect to any studies using federal funds.

For example, OHRP's Policy and Guidance Library contains analysis of areas of the regulations that often cause confusion. For example, OHRP's Guidance on Research Involving Coded Private Information or Biological Specimens assists practitioners in identifying when patient consent is required before health information is used for research.

Guidance regarding how to distinguish quality improvement activities which do not require patient consent from research projects which may require consent can be found in the agency's FAQs.<sup>23</sup> The distinction can be so challenging at times, the renown institutions have unwittingly run afoul of the regulations.<sup>24</sup>

In addition to guidance documents in the form of text discussion, the OHRP also provides a series of decision tree charts which address 11 different questions regarding application of the regulations. These include outlines regarding when informed consent requirements can be waived or altered.<sup>25</sup>

### b. NIH's Office for Human Subject Research

The National Institute of Health's Office for Human Subject Research assists investigators working in NIH's intramural research program with regulatory compliance.<sup>26</sup>

#### c. Office of Research Integrity

ORI provides assistance to institutions responding to an allegation of research misconduct through its Rapid Response for Technical Assistance ("RRTA") program to facilitate high quality and well-documented investigations and help resolve research misconduct cases promptly.

## 2. Other Industry Support Resources

### a. The Centers for Law and the Public's Health

The Centers for Law and the Public's Health is a collaborative effort of Johns Hopkins and Georgetown Universities. Founded in October, 2000 as a CDC Collaborating Center in Public Health Legal Preparedness, and in June, 2005 as a WHO/PAHO Collaborating Center in Public Health Law and Human Rights, it is a primary, international, national, state, and local resource on public health law, ethics, human rights, and policy for public health practitioners, lawyers, legislators, judges, academics, policymakers, and others. It provides education, supports research and disseminates information.<sup>27</sup>

### b. The Network for Public Health Law

The Network for Public Health Law provides resources including legal assistance to assist government officials; public health practitioners; attorneys; policy-makers; and advocates. The Network strives to maximize the value of public health laws in improving public health.<sup>28</sup>

## 3. New and Traditional Approaches

### a. Hodge Enhanced Criteria Methodology

Despite multiple guidance documents provided by agencies and institutions well versed in human subject research and privacy protections, continued debates regarding when public health activities are research and when patient consent is required inspired one expert to propose a methodology using enhanced criteria based upon: legal authority, intent, responsibility, participation benefits, experimentation and subject selection.<sup>29</sup> Professor James Hodge<sup>30</sup> created the enhanced methodology that is designed to assist public health agencies and officials and efficiently incorporates specific attention to each of the underlying principles that led to the design of applicable regulations. It also provides useful insight for providers engaged in public health activities.

**b. Health Information Technology Policy Committee**

The Health Information Technology Policy Committee is the advisory body for the National Coordinator of Health Information Technology. It was charged by Congress to provide short term and long term recommendations based upon the American Resource Recovery Act (ARRA) and the Accountable Care Act (ACT.) In its October 18, 2011 letter to the National Coordinator, the Committee endorsed the fair information practices, articulated by the Office of the National Coordinator.<sup>31</sup> Compliance with the recommendations facilitates the secondary uses of treatment information in a manner which is most likely to build and maintain the public's trust in evolving federal policy. The Committee also discourages the overreliance on consent, as doing so can "inappropriately shift the burden for protecting privacy onto patients."<sup>32</sup>

Recommended fair information practices<sup>33</sup> include:

- Limit the amount of information collected to what is necessary.
- Limit the number of people who have access to those performing the research.
- Adopt and adhere to specific retention policies with respect to the data.
- Adopt basic security protections consistent with the privacy risks associated with inappropriate exposure of the data.

**II. Health Data and Health care Reform**

The health care delivery sector (providers, payers) and public health professionals traditionally collected and used differing health care data for differing purposes. Public health has seen changes driven by increased patient protections and the need for more timely analysis. The health care delivery side has been changing its practices and perspectives in an effort to calibrate cost and outcomes. A brief overview of some major turning points in the last 20 years demonstrates how the lines of focus and purposes of these key players are converging: public health researchers who may have concentrated on populations will need to look more at individual patients and providers; payers will need to accelerate their focus on quality more than quantity; and providers will find themselves newly gathering and manipulating data.

**A. Latest Round Of Reform Started With Quality Control**

A public health research project in the late 1990s touched off a firestorm in revealing a level of medical errors few had realized. This research project culminated in the published report "To Err Is Human," by The Institute of Medicine.<sup>34</sup> This 1999 report further galvanized the

"pay-for-performance" movement amongst many health care payers and policymakers who saw costs escalating without commensurate quality improvement; in some cases, with unacceptable quality. A few years earlier, the Dartmouth Institute for Health Policy and Clinical Practice at Dartmouth University began a series of studies using Medicare data that revealed significant disparities in utilization of services, cost, and outcomes.<sup>35</sup>

The 1990s also saw emergence of a movement in health care delivery with a more central role for research and data: evidence based medicine ("EBM"). EBM as a philosophy aims to apply the best available evidence gained from the scientific method to clinical decisionmaking.<sup>36</sup> It seeks to assess the strength of evidence of the risks and benefits of treatment, including lack of treatment and diagnostic tests. Evidence quality may be assessed based on the source type (from meta-analyses and systematic reviews of double-blind, placebo-controlled clinical trials at the top end, down to conventional wisdom at the bottom), as well as other factors including statistical validity, clinical relevance, currency, and peer-review acceptance. EBM recognizes that many aspects of health care depend on individual factors such as quality and value-of-life judgments, which are only partially subject to scientific methods. Another, more "public health," aspect of EBM seeks to clarify those parts of medical practice that are in principle subject to scientific methods and to apply these methods to ensure the best prediction of outcomes in medical treatment, even as debate continues about which outcomes are desirable.

**B. Health Care Reform and How Data Underlie the Convergence of Providers, Payers, and Public Health**

As with public health research and practice, health care reform requires the availability and analysis of data. Payers, patients, and policymakers are looking to improve the efficiency, transparency and quality of care and reduce fraud, and public health professionals are looking to improve the overall health of our populations. The latest round of health care reform legislation envisions a national strategy and priorities for improved quality and cost effectiveness through reporting with an interagency working group, development of quality measures, data collection, and public reporting.

**1. The American Recovery and Reinvestment Act**

The first piece in the new national health care strategy came in early 2009 with the American Recovery and Reinvestment Act ("ARRA").<sup>37</sup> ARRA provided many different economic stimulus opportunities, one of which was \$19.2 billion marked for health information technology. The underlying premise of these healthcare provisions in ARRA is that the adoption of health information technol-

ogy in high priority areas such as electronic prescribing, interoperable electronic health records, and quality measure reporting will improve patient safety and the quality of healthcare, providing better outcomes for less cost.

A subpart of ARRA is known as The Health Information Technology for Economic and Clinical Health Act (“HITECH”).<sup>38</sup> HITECH significantly modifies HIPAA by adding new requirements concerning privacy and security for health information that materially and directly affect more entities, businesses, and individuals. Specifically, HITECH:

- expands the definitions of “business associates.” HITECH includes as “business associates” organizations that transmit protected health information and require access on a routine basis to such information.<sup>39</sup>
- extends HIPAA security standards and penalties to business associates.<sup>40</sup>
- establishes new security breach notice requirements.<sup>41</sup>
- entitles individuals to electronic copies of health information at a cost not greater than the entity’s labor costs.<sup>42</sup>
- prohibits a health plan, health care provider, or business associate from receiving payment for an individual’s protected health information without authorization from the individual.<sup>43</sup>

HITECH also directed HHS to develop regulations to establish a Medicare and Medicaid incentive payment program for providers when they adopt certified electronic health record technology and use it to achieve specified objectives.<sup>44</sup>

HHS published the first of such regulations on July 28, 2010. This regulation specifies the criteria hospitals must meet to qualify for stage 1 of the 3-stage incentive program outlined by HITECH. Program objectives do not merely assess whether the hospital has electronic health record technology installed; the program is designed to evaluate whether electronic health record technology is being utilized in a meaningful way. The rule is thus commonly known as the “Meaningful Use” Rule.

The three main stages of the Meaningful Use Rule contemplate an evolution from initially capturing and using health information in a structured format to exchanging health information, tracking clinical conditions, and using health information technology for order entry, result reporting and improving quality at the point of care.

CMS, the federal agency responsible for enforcing HITECH, has provided 38 specialty-specific quality mea-

asures from which providers may choose for reporting to demonstrate meaningful use. Only the actual reporting is required. Meaningful Use does not establish quality benchmarks or minimum performance standards.<sup>45</sup>

Another thing Meaningful Use does not do is establish privacy and security requirements that could conflict with those under HIPAA.<sup>46</sup> Rather, CMS has included the requirement that providers and hospitals protect electronic health information by conducting or reviewing a risk analysis under the HIPAA Security Standards.<sup>47</sup>

Providers face compliance documentation and due diligence in attesting to compliance with the Meaningful Use requirements. Providers attesting to meaningful use without actually demonstrating Meaningful Use may be subject to liability under the Federal False Claims Act.<sup>48</sup>

## **2. Patient Protection and Affordable Care Act**

Following ARRA’s provisions addressing health information data and technology was specific health care legislation affecting nothing less than a paradigm shift in how healthcare is delivered in our country. This legislation, the Patient Protection and Affordable Care Act (“PPACA”), was signed by President Obama on March 23, 2010.<sup>49</sup> PPACA puts in place comprehensive health insurance reforms to secure the payment of health care for most of our population and creates delivery paradigms to help secure cost-effective healthcare as well as a healthier population. Implementation of the new incentives requires the collection and analysis of data by all players in the healthcare system.

## **3. New Health Care Delivery Models**

There are two main health care delivery structures developed or refined with PPACA requirements in mind: accountable care organizations (“ACOs”) and medical homes.

### **a. ACOs**

CMS defines an ACO as a group of doctors, hospitals, and other health care providers who come together voluntarily to provide coordinated, high quality care to their Medicare patients.<sup>50</sup> The goal of coordinated care is to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds both in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

An ACO requires electronic health records, data management, personal health records, and health information exchanges. Each of these elements must provide “traditional” capabilities. For example, electronic health records



must support the documentation of a patient's problems and e-prescribing, and health information exchanges must enable the transfer of discharge summaries and procedure reports between providers.

In addition to application systems such as the electronic health record, ACOs will need to implement sophisticated systems to manage data. Data management will require the development of new data use and management procedures. As the level of electronic health records interoperability increases, the data repositories of an ACO will expand to include data generated by multiple-provider legal entities. Policies and procedures will need to address issues such as secondary use of data where multiple organizations are contributors. ACOs will also need to share with and handle data from patient personal health records and state health information exchanges.

Relatively few health care organizations have adopted the core applications needed for an ACO at this time.<sup>51</sup> However, the HITECH incentives are likely to increase their use and to establish the regional health information technology necessary to foster ACO development and improve performance.

Quality data and data management infrastructure may be the most important ACO asset. For example, if payment is based on conformance to chronic disease protocols, the organization must have data that illustrate how well it conforms to those protocols. An ACO's performance may be severely hindered if its data are of poor quality—even if its clinicians are using a sophisticated electronic health record.

#### **b. Medical Homes**

Another touted model of health care delivery under healthcare reform is the “medical home.” The formal concept of “medical homes” has existed for several years, but has spread quickly under healthcare reform.<sup>52</sup> The Agency for Healthcare Research and Quality defines a medical home not simply as a place but as a model of the organization of primary care that delivers the core functions of primary health care. The medical home, also known as the patient-centered medical home, is a team-based health care delivery model led by a primary care physician that provides comprehensive and continuous primary medical care to patients with the goal of obtaining maximized health outcomes.<sup>53</sup> While traditional managed care systems focused on vertical integration with gatekeeping and specialist referral, medical homes focus on more horizontal integration.

The method of bringing patients to medical homes is similar to that of ACOs. Some medical home models involve patients choosing providers who are willing and able to serve as their “medical home.” Other programs

may assign patients to a medical home based on data of existing delivery patterns. Data regarding cost and quality outcomes of medical homes will be critical in determining the efficacy of these programs.

#### **4. Proposed Revision of the Common Rule**

On the heels of the health care delivery reform legislation and new models, the public health/research sector is preparing to undergo a significant shift as well. HHS and the Office of Science and Technology have proposed reforms to the Common Rule.<sup>54</sup>

The proposed changes include requiring consent for research use of any biospecimens collected, and establishing mandatory data security and information protection standards to eliminate the need for Institutional Review Boards to review informational risks of research. The data security standards are being designed to mirror those in HIPAA/HITECH.<sup>55</sup>

#### **C. Criteria for Success Under Healthcare Reform**

Public health professionals, providers and payers will gather, analyze, and use data to meet the needs of health care reform and must be prepared to share their data and adjust to new transparency. Each of these health care pillars will further need to readjust their traditional focus. Public health professionals traditionally focused on populations will also need to analyze individualized data. Providers focused on each individual patient will need to look at aggregate data as to regions and populations to benchmark and be accountable for their care. Payers will be looking at claims history of individual providers as well as individual patients, and will shift from transaction-based data to clinical data to measure performance and outcomes.

Research will need to be significantly more responsive to demands for findings that are timely and actionable. The health care research enterprise typically has been rich and innovative, but also fragmented and supply-driven, much like health care itself. Meeting the pressing information needs of health care reform will require a clear strategy and close collaboration among government agencies, private data organizations, and researchers producing needed data. These needs also will require strong coordination between the producers and users of that data so that researchers and analysts can, to the extent possible, anticipate and meet policymakers' need for the right information at the right time.

The success of this attempted paradigm shift in health care delivery depends on many factors. Cooperation and collaboration between the sectors of public health and healthcare delivery are chief factors. There is much the two sectors can learn from each other to help move to the same goal: a healthy population at a reasonable cost.

### III. A Provider's Perspective

Historically, the practice of public health was founded and predicated on identifying community outbreaks of communicable diseases. While early efforts pre-date the concepts of modern germ theory and hence, effective diagnostic testing, effective treatment options, and to a large degree effective vaccination options, they did establish the routine use of case reporting for communicable disease surveillance systems and attempts to establish a sanitary code.

As the practice of medicine and microbiology matured, public health practice evolved into the beginnings of organized publicly funded programs that continued to largely target the prevention and control of communicable diseases. Appreciating the societal benefit from disease prevention relative to the individual's right to privacy, public health codes were promulgated that mandated physician case reporting to governmental public health entities. Reported cases were used in an aggregate manner to muster resources such as mass vaccination programs to limit disease transmission. In addition, case reporting using identified patient information was used to guide outreach efforts to ensure that identified cases were appropriately treated or quarantined and that susceptible contacts were either quarantined, prophylaxed, vaccinated, or effectively treated. This approach has been highly successful in controlling numerous communicable diseases, such as tuberculosis, sexually transmitted diseases and meningococcal meningitis and continues to be part of the present day armamentarium of public health practice.

The effectiveness of communicable disease control efforts is well documented and they have significantly transformed the epidemiology of many communicable diseases. These efforts continue to be useful in addressing emerging community epidemics of AIDS, H1N1 influenza and Hepatitis C.

In the past 10 years, the mission of public health departments has incorporated numerous dramatic changes. Control of infectious diseases has extended into the acute care hospital and long term care facility settings and the last five years have seen an almost explosive introduction of initiatives designed to reduce the prevalence of hospital acquired infections and multiple antibiotic resistant bacteria.

Increasingly, public health practitioners have embraced a broader mission to promote community "wellness" through preventative medicine measures, including campaigns designed to modify high risk behaviors as diverse as smoking, unprotected sex, excessive alcohol use, injected drug use, failure to use seatbelts, driving

while impaired, and even dietary habits that drive the current epidemic of obesity. There are renewed efforts to address the fact that in spite of the availability of highly effective and safe vaccines for a wide variety of infectious agents, community vaccine coverage rates remain discouragingly low. In addition, progressive public health practitioners are targeting the optimization of care provided to patients with chronic non-infectious diseases, such as diabetes, in order to prevent the considerable toll of morbidity and mortality among patients with poor glucose control.

Finally, public health practitioners have embraced the creation of electronic data bases containing patient-specific information. Some have initiated discussions of how linkage to other existing privileged electronic data bases, such as those maintained by hospitals and health care providers, could be used to assess health care needs and provide opportunities to improve compliance with preventative health measures across the continuum of care.

Increasingly, public health practice is destined to be on a collision course with the mandates of compliance with human subject research protections and patient privacy standards, similar to that experienced by the patient safety and quality improvement movement. This interface will be poorly served by the currently existing patchwork of health codes and legislated empowerment of government public health activities that regulate the use of patient specific identifiers and define the scope of practice. While cognizant of the need to protect against potential abuses, placing unnecessary obstacles in the path of efficient and effective public health practices will not serve us well. A careful review of current New York State and New York City legislation supporting public health access to patient specific data, some of which dates to the early 1930s, is necessary and they should be consolidated and updated to accommodate modern practice.

For instance, a recent New York City Department of Health initiative established a registry for childhood vaccinations. All pediatricians are mandated to enter information about any administered childhood vaccination via password-protected access to the system. Data entry requires keying in patient specific identifiers to confirm patient identity and once access is granted the physician can also review the patient's prior vaccination history. This initiative has been highly successful in increasing pediatric vaccination rates, improving compliance with pediatric vaccination schedules, and preventing unnecessary duplicate vaccinations when parents are unable to document prior vaccination activity during the visit. Is this system HIPPA compliant? How do real or perceived HIPPA issues impact this initiative? Would this system even be functional, if it was interpreted that sharing prior

vaccination history was a violation of patient privacy? Does the existing public health legislative mandate that allows the establishment of this registry in New York City extend to other jurisdictional areas of New York State?

A second example illustrates the potential conflict of public health practice with human subject's research issues. New York State established a legislative mandate for all hospitals and nursing homes to establish a "standing orders" protocol to provide for influenza and pneumococcal vaccination of inpatients. Conceptually, the legislation was appropriately targeted in that hospital and nursing home patients are among community members at the highest risk for contracting and dying of influenza and pneumococcal pneumonia. Their physicians have historically vaccinated only a small percentage of them. The protocol provided for screening of eligible patients by non-physician staff and activation of a "standing order" for vaccination of consenting patients under the signature of a physician supervising the program. The legislation specifically required a review of the CDC's Vaccine Information Sheet for each type of vaccine offered and patient consent prior to vaccination.

As these programs were initiated, many reported unacceptably high refusal rates approaching 33% of eligible patients, even though the vaccines were offered for free. Patient surveys querying reasons for refusal identified that the most common reason was that patients paradoxically did not understand that they were at high risk for the disease. Review of the Vaccine Information Sheet revealed that it did not adequately identify inpatient risk for disease and subsequent patient consensus groups were used to develop an ancillary one-page information sheet that addressed the issue. Use of the ancillary form reduced patient refusal by approximately 50%.<sup>56</sup> Should this activity, designed to optimize compliance with an existing standard of care, and using methodologies routinely employed by marketing and educational consultants, now be construed as human subject research? Or is it effective public health practice? Would it be research if the evaluation phase included randomization of patients, or if the findings are shared with other practitioners by publishing them?

It can be argued that the scope of modern public health needs to be reexamined and appropriate authority established to promote innovative, evidence-driven, and cost effective practice that will optimize outcomes and community benefit. Achieving this goal will require some accommodation of patient privacy and human subject principles, but clearly must carefully define when the potential for community benefit exceeds the interest and rights extended to any individual.

#### IV. Conclusion

The ability to share information between providers is essential to the advancement of medical knowledge. The increased ability to generate and measure quality data makes evidenced based medicine, across the continuum of care, a feasible reality. Patients and communities are best served in a system that does not overly restrict the efficient flow of necessary information in the interest of confidentiality. Nonetheless, reasonable controls regarding the amount of information and the manner of disclosure are important to minimize the risk of harm to patients. As our technology increases the amount of information available about patients and the ease of disclosure, regulations to prevent abuse of the trust patients place in their providers are following suit.

Today the daily challenges to distinguish when disclosures of patient information require patient consent take place inside and outside health care settings. Within a provider's office or medical center distinctions must be made between disclosures for treatment and disclosures for quality care, research and public health practice. Outside the health care delivery settings public health practitioners must distinguish research and practice.

Risks from medical treatment and the use of health information will always exist. Regulations have strived to ensure that these risks are not taken lightly and are minimized to the greatest extent possible. Parties responsible for enforcing patient protections and researchers committed to advancing medicine have done fairly well navigating the web of interrelated regulations. Ongoing efforts to further enhance protections and control regulatory obstacles to progress should be applauded.

While health care reform initiatives are dependent upon increasing amounts of health care data, they do not make every provider or public health practitioner a researcher who must clear every data use with an IRB. Most of the data providers will be required to report under health care reform laws is de-identified or falls within permissible uses for health care operations and public health activities under HIPAA. Nonetheless, providers and public health practitioners must remain alert to research activities which may require patient consent. Patients should also welcome opportunities to participate in the research that will determine the future success of our health care.

#### Endnotes

1. 45 C.F.R. § 46.101 et seq. (2009).
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**The authors wish to thank Lia E. Mulligan, Esq. of Tarshis, Catania, Liberth, Mahon & Milligram, PLLC Newburgh, NY for her assistance with this article. Opinions expressed in this article are that of the authors and not necessarily their affiliated organizations.**

# eMOLST and Electronic Health Records

By Patricia A. Bomba and Katie Orem

## Introduction

This article reviews the development and current state of the electronic Medical Orders for Life-Sustaining Treatment (eMOLST) and the future vision of a statewide registry as the optimal solution for New York State. The key quality and patient safety elements of the eMOLST application seamlessly integrate the clinical process, including a discussion on goals for care, with the legal requirements under New York State Public Health Law and Family Health Care Decisions Act. The eMOLST provides a system-based solution for health systems and the community that ensures accessibility of the eMOLST form, and improves provider training and satisfaction, as well as clinical and legal outcomes. Recommendations are made for statewide development and implementation of the eMOLST Program. The ultimate goal is to ensure patient preferences for care are honored at the end of life.

## Summary

Honoring patient preferences is a critical element in providing quality end-of-life care. Medical Orders for Life-Sustaining Treatment (MOLST) is a program designed to improve the quality of care seriously ill patients receive at the end of life by translating patient goals for care and preferences into medical orders. MOLST is based on effective communication between the patient, his or her health care agent or other designated surrogate decision-maker, and health care professionals that ensures shared, informed medical decision-making. The process results in documentation of medical orders on a bright pink form that health care professionals must follow. MOLST is a standardized community-wide form that transitions with patients across all care settings.

As a result of a New York State Department of Health (NYSDOH) HEAL 5 (Health Care Efficiency and Affordability Law) grant, a secure web-based eMOLST application was developed. The eMOLST application documents the clinical process, including a discussion on goals for care, with the legal requirements under New York State Public Health Law (NYSPL). The eMOLST application streamlines the workflow to complete the requirements for a legal medical order with automated user feedback for quality review, notification of missing information, and training tools for users.

The eMOLST application will render an electronic version of the current paper-based NYSDOH-5003 MOLST Form and the appropriate MOLST Chart Documentation Form for adults or minors along with the Office for Persons with Developmental Disabilities (OP-WDD) checklist for developmentally disabled individuals

without medical decision-making capacity. These forms are made available to providers through the Rochester Regional Health Information Organization (RHIO). The role of RHIOs in New York State is to transfer health information across clinical care settings and incorporate patient-driven data in a Health Information Exchange (HIE). Multiple RHIOs across New York will connect to each other through a network called SHIN-NY. The Rochester RHIO plans to attach signed eMOLST forms to its XDS.b document registry.

In keeping with New York State's vision for open-system solutions, the eMOLST application is being developed following open architectural principles for the benefit of the community and other RHIOs across the state. The long-term vision of this project is to build a New York State eMOLST registry by leveraging the SHIN-NY network and serve as a model for the nation.

To clarify, eMOLST is an electronic MOLST form that can be completed on a computer, printed for a patient, stored in an electronic medical record (EMR) and transmitted to a registry of forms. A MOLST Registry is an electronic database centrally housing MOLST forms to allow 24/7 access in an emergency. In New York, our eMOLST application combines both the MOLST process with form completion while also housing the New York State eMOLST Registry. Learn more on [nysemolstregistry.org/](http://nysemolstregistry.org/).

By moving the MOLST form to a readily accessible electronic format, health care providers, including emergency medical services (EMS), will have access to MOLST forms at all sites of care including hospitals, nursing homes and the community. This approach will allow for EMS to view the eMOLST form in the event of an emergency and will allow other systems to view the form at the time of need, as the document is shared across the care continuum.

In summary, in terms of MOLST form creation, validation and generation, eMOLST is the optimal solution to assist providers in having the MOLST discussion, documenting the clinical steps and fulfilling legal requirements under NYSPL. The inherent quality assurance and interoperability features of eMOLST reduce overall liability and risk.

## History of MOLST and eMOLST in New York State MOLST Program

The MOLST Program began with creation of the original MOLST form in November 2003. MOLST, adapted from Oregon's Physician Orders for Life-Sustaining



Treatment (POLST), combines resuscitation instructions and other life-sustaining treatment while complying with NYSPHL.<sup>1</sup> Regional adoption and collaboration with NYSDOH began simultaneously in March 2004. A revised form consistent with New York State law was approved by the DOH for use as an institutional DNR in *all* health care facilities throughout New York State in October 2005<sup>2</sup> and the 8-Step MOLST Protocol was introduced to standardize the MOLST process.

With passage of the MOLST Pilot Project Legislation (2005)<sup>3</sup> and Chapter Amendment (2006),<sup>4</sup> MOLST was approved for use as a Nonhospital Do Not Resuscitate (DNR) and Do Not Intubate (DNI) form in the community in Monroe and Onondaga counties. After a successful three-year MOLST Pilot Project, Governor David Paterson signed Section 2977(13) into NYSPHL in 2008. This law authorized the use of MOLST as an alternative form for issuing a nonhospital order not to resuscitate (in place of the standard form) and for issuing a non-hospital do not intubate order, thereby, changing the scope of practice for EMS across New York State.<sup>5</sup>

In March 2010, a seventeen-year effort to enact legislation that would improve end-of-life decision options culminated in the passage and signing of the Family Health Care Decisions Act (FHCDA), a New York State law that enables a patient's family member to make health care decisions when the patient is not able to do so.<sup>6</sup> The key provisions of FHCDA became effective on June 1, 2010.<sup>7</sup> NYSPHL section 2977(13) was repealed and a new NYSPHL, Article 29-CCC, was created to govern Nonhospital DNR Orders, including the MOLST.<sup>8</sup> The NYSDOH also revised the MOLST form (DOH-5003) in June 2010 to make it more user-friendly and to align the form with the procedures and decision-making standards set forth in FHCDA.<sup>9</sup>

FHCDA was followed by the enactment of the Palliative Care Information Act (PCIA)<sup>10</sup> and the Palliative Care Access Act (PCAA) in 2011. Under the PCIA, an attending health care practitioner must *offer* to provide information and counseling about palliative care to patients with a terminal condition, including the range of options appropriate to the patient, prognosis, risks and benefits of various options, and the patient's "legal rights to comprehensive pain and symptom management at the end of life."

The PCAA obliges hospitals, nursing homes, home care agencies as well as enhanced and special needs assisted living residences to establish policies and procedures regarding palliative care, including access to information and counseling and facilitating access to appropriate palliative care consultations and services.<sup>11</sup> Passage of the PCIA and PCAA will ensure that patients

and loved ones will be provided with information on the key pillars of palliative care: advance care planning, pain and symptom management, and caregiver support. Decisions regarding hospice care, including the withdrawal or withholding of life-sustaining treatment, under FHCDA became effective September 19, 2011.<sup>12</sup>

Advance care planning, including having a patient-centered discussion on goals for care where MOLST completion is one element, is a key pillar of palliative care and assists providers and health care facilities meet the new legal requirements of the PCIA and the PCAA.

### eMOLST

A NYSDOH HEAL 5 grant was awarded to the Rochester RHIO in 2008. Included in the HEAL 5 grant was funding to initiate a New York State Registry for advance directives and MOLST forms.

When work began, paper MOLST forms had to be accompanied by supplemental forms (one for adults without capacity and another for minor patients) to support documentation of the process and fulfill legal requirements. The MOLST process was used in hospitals, nursing homes, assisted living facilities and hospices as well as by physicians in the community. Many hospitals and nursing homes were already scanning paper MOLST forms and attaching them to a patient's electronic health record (EHR), but this information was not easily available outside of their institution and did not eliminate the potential for incompatible medical orders on the MOLST form.

The core value of making the MOLST form available to the RHIO (and thereby the HIE) is that the HIE can make MOLST orders available to other providers and institutions at the point of care—thus ensuring that a patient's wishes about end-of-life treatment are honored. As a NYDOH-funded service through the HEAL 5 grant, the intention was to create an electronic version of the MOLST application that can be queried by any number of other HIEs or other clinical systems.

A major goal of the project was to ensure broad acceptance. Thus, the application would need to be developed in such a way that the barriers to adoption were minimized and the application best fit institutional workflows, while balancing data requirements and business logic in keeping with the MOLST program and legal requirements under NYSPHL.

A range of approaches were initially considered including scanning MOLST forms in with or without Optical Character Recognition (OCR). Another approach considered was the creation of the MOLST form as an electronic web-based data collection form with more error checking and logic prompts to better ensure data quality

and compliance. As part of the early analysis and design, the various solutions were reviewed in terms of the functions required to support the approach, as well as the positive and negative aspects of each approach and their likely adoption rates. In addition, the potential solutions were presented to representative institutions for feedback and to help finalize the initial direction of the project.

Development of eMOLST, a secure web-based application with automated workflow, emerged as the optimal community solution with three major goals:

- **Assure Accessibility**—An electronic registry is created in the Rochester community. The long-term vision of this project is to build a New York State eMOLST registry by leveraging interoperability between New York State RHIOs using the SHIN-NY network.
- **Improve Quality Assurance**—There are built-in quality controls to ensure accuracy of form completion. It is designed to streamline the workflow around completing the information for a legal medical order with automated user feedback for quality review, notification of missing information and training tools for users. The electronic version of the MOLST form is legible. Incompatible orders are eliminated; for example, both “Cardiopulmonary Resuscitation” and “Do Not Intubate” cannot both be chosen on an eMOLST form as this combination of orders is clinically impossible. Similarly, both “Cardiopulmonary Resuscitation” and “Comfort Measures Only” cannot be chosen.
- **Build Quality Metrics**—Integration of outcome measurement and trend reporting is available.

With passage of the Family Health Care Decisions Act, the legal requirements changed effective June 1, 2010 and the supplemental MOLST forms became obsolete. A public eMOLST Preview was held on October 19, 2010. As a result of site visits with providers in early 2011, additional functionality was built into the application to integrate the clinical steps, legal requirements, and documentation of the discussion.

## eMOLST Application Functions

The eMOLST application allows authorized health care professionals to access the system and create, review and renew, update and view patients’ eMOLST forms. Physicians can electronically sign the form. The details and security of eSignatures will be addressed later in this article. All consents obtained when completing an eMOLST are verbal, unless a paper-to-eMOLST conversion is taking place, in which case the original consents can be documented, unless new consents are obtained. Users can keep track of eMOLST forms completed for

their patients, and receive messages about which patients are ready for review and renewal or updates to MOLST orders.

A PDF version of the form will be available to print when the provider finishes entering information and should be printed on bright pink paper for the patient. In the Rochester RHIO area the PDF will be sent to and viewable through the Rochester RHIO’s XDS.b document registry and will eventually be exchanged with other RHIOs in New York State via the SHIN-NY network.

The eMOLST application supports the completion of Chart Documentation Forms that align with the NYSDOH Legal Requirements Checklists for Adult and Minor Patients and the OPWDD checklist for individuals with developmental disabilities who lack medical decision-making capacity. A PDF will be generated for the OPWDD Checklist that MUST be attached to the MOLST form. PDFs will also be generated for the Chart Documentation Forms for inclusion in the medical record.

The eMOLST application renders in iOS Safari as well as all Android-based browser options on the market, making eMOLST tablet-friendly. Furthermore, a simplified eMOLST mobile application is in development and will be available for iPhones and Android phones. Unfortunately due to technical limitations, BlackBerry devices are not supported.

## eMOLST Training Tools

In order for eMOLST to sustainably grow across New York State, training tools were developed to ensure that users can quickly and easily understand the application. There are two primary eMOLST training tools for clinical users of the eMOLST application: eLearnings and the eMOLST Manual for Clinicians.

eLearnings are available through the “Tutorials” link listed on every page in the eMOLST application. This link redirects users to the CompassionAndSupport.org eMOLST web page. This eMOLST page is also directly available through the MOLST Training Center on CompassionAndSupport.org. The eLearnings walk users through the process of understanding eMOLST, section by section. Most eLearnings are approximately one or two minutes long and address specific issues, such as completing the Discussion section, or how to convert paper MOLST forms to eMOLST. The eLearnings show users the necessary eMOLST screens for the topic discussed and show exactly where users need to click to appropriately complete the eMOLST process. Voiceovers in the eLearnings provide instruction throughout the short videos.

Another component of eMOLST training is the eMOLST Manual for Clinicians. This is a pdf document that can be easily accessed from a link in the eMOLST

application and eMOLST web page on CompassionAndSupport.org. During the initial eMOLST launch trainers noted that certain users who were less accustomed to digital form completion were also not as comfortable with watching an eLearning video and then following the same steps in the application. These users preferred something tangible and written that they could print and follow until they used the eMOLST application regularly and became more comfortable. As a result of this user feedback, an eMOLST Manual for Clinicians was developed. The content of the eLearnings and the eMOLST Manual for Clinicians is identical; however, the preferred methods for learning how to use eMOLST varied, so both were developed to meet the different needs of different users.

The addition of eLearnings and the eMOLST Manual for Clinicians to the eMOLST application are critical parts to ensure that eMOLST growth across New York State is scalable and sustainable. The presence of these web-accessible training tools ensures that clinicians from across the state can learn to use eMOLST without an official training session held by someone who already knows how to use the application. Instead, users can explore the application themselves and learn as they go. For example, a user could watch the eLearning on completing the Discussion section of the eMOLST form and then go on to complete that section with a patient. Or, if a clinician prefers, he or she can have the eMOLST Manual for Clinicians in-hand as he or she works in the eMOLST application. Both the eLearnings and the eMOLST Manual for Clinicians are also especially helpful for users who have not been active in the application recently and need a quick refresher on how to appropriately complete a certain part of the eMOLST process.

## Security, Privacy and Confidentiality

eMOLST is a web-based application, securely served over an HTTPS://connection. Currently, the eMOLST application is hosted in a physically secure datacenter maintained by Excellus BlueCross BlueShield. The database holds data at rest in an encrypted format. Any links between patient identifiers and patient data are also encrypted.

The database and application are two distinctly separate entities. This means no data may be decrypted directly from the database without the application. The decryption keys are stored in the application, and data cannot be decrypted from the database without it.

Access and information transmitted through the eMOLST application and the Rochester RHIO comply with HIPAA, NYSDOH privacy rules and NYSPHL.

## eSignature

Physicians can electronically sign the form. An e-signature, as defined by the U.S. Commerce E-SIGN Act, is “an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.” An e-signed document “may not be denied legal effect, validity, or enforceability solely because it is in electronic form.” Examples of e-signature technologies and processes include:

- Entering a PIN at an ATM, or using a PIN to sign online forms such as the Free Application for Federal Student Aid (FAFSA);
- Using an electronic tablet to sign a credit card receipt; and
- “Clickwrap” (clicking a button indicating acceptance of a license agreement before installing software, etc.).

The design for e-signatures in eMOLST features:

- User authentication methods and a closed, trusted user registration model;
- Additional authentication before signing the form;
- A “clickwrap” method to indicate user intent and acceptance when making the signature;
- Embedding signature artifacts in the final digital/printed form;
- Graphical renderings of signatures embedded and watermarked in the final form;
- Detailed audit logs recording the form discussion, completion, and signing;
- The ability to cross-reference the completed form in multiple formats and repositories;
- Standards and processes to ensure EMS and other practitioners can easily recognize and trust a valid MOLST form produced by the eMOLST system.

A multi-variable re-authentication method minimizes cost and risk by integrating processes and software, preventing errors, and standardizing results. This approach is also scalable and sustainable by following proven deployment models and allowing a standardized e-signature approach for eMOLST statewide.

## eMOLST Analytics, Data and Opportunities for Future Research

There is a specific Analytics function developed in the eMOLST application. The Analytics section allows users



to view sections of completed eMOLSTs in aggregate. For example, if there are 100 patients with eMOLSTs at a facility and 90 patients chose DNR it would be easy to see that in the Analytics section. Users cannot see who those 90 patients are, though, as the data is de-identified and aggregated. The Analytics function will be useful to identify trends or correlations between different elements on the eMOLST form. For example, users might want to know whether their patients' choices regarding resuscitation instructions and life-sustaining treatment correlate well with goals for care, prognosis and/or functional status. Additionally, a health system may wish to identify whether MOLST forms are being created primarily in the hospital, the nursing home or the community, and who is making the decisions (patient, health care agent, public health law surrogate, minor's parent/guardian or §1750-b surrogate.) These questions, in addition to many others, can be answered using the eMOLST Analytics function. Targeted educational interventions can be designed and implemented.

The Analytics function is also helpful for facilities that want to look at eMOLST from a quality assurance (QA) or quality improvement (QI) perspective. If the person who does QA/QI activities at a particular facility is not involved with patient care then a special profile can be set up in the eMOLST application which will prevent that person from accessing identifiable HIPAA-covered data, while still allowing them to access necessary information about eMOLST form completion for their facility's patients.

Much of the data that will be aggregated in the eMOLST application's Analytics section is not currently available without doing time-intensive individual chart reviews. Making this de-identified information easily accessible will help facilities improve the quality of care their patients receive. Moreover, facilities will be able to easily access this data for submission for Joint Commission Advanced Certification in Palliative Care. In the future, Institutional Review Board (IRB) approval will be sought to answer broader research questions about end-of-life decision-making.

## Interoperability Requirements

For participating entities using an EHR or Electronic Medical Record (EMR) system, interoperability is required to ensure that patient wishes are honored, and that there is no loss in transition of care. A direct, interoperable connection between the EHR/EMR and eMOLST fulfills this requirement and supports the goals of the MOLST program.

Examples of interoperability include:

1. Single Sign On (SSO) between the EMR and eMOLST to ensure an uninterrupted electronic workflow.
2. Scan/Attach of printed eMOLST documents into the patient record in the EHR/EMR to ensure accessibility at the time of need.
3. Querying the Rochester RHIO to obtain current copies of eMOLST documents from the XDS.b document registry.

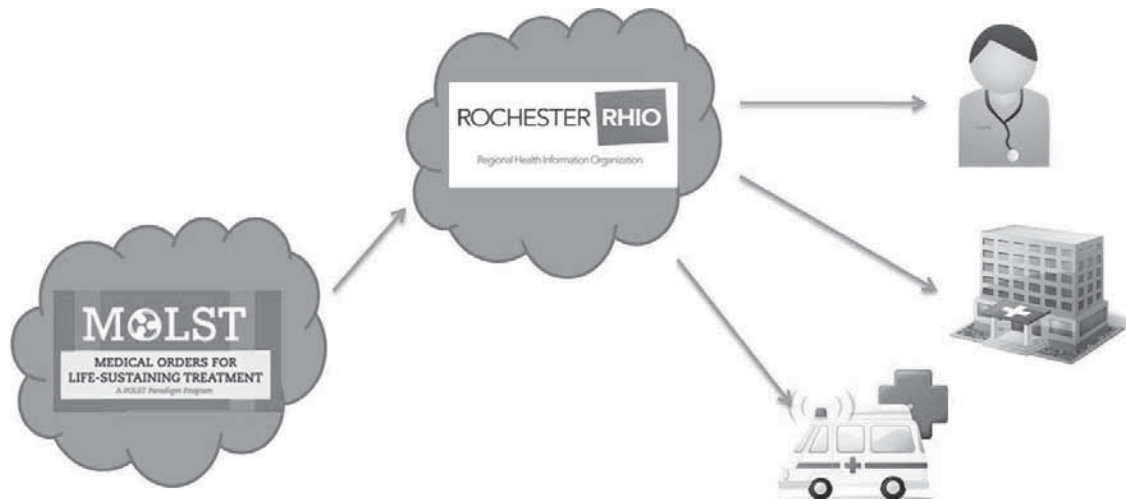
The EMR system should have the ability to rapidly receive and accurately store and display the external MOLST forms within that patient's EMR. MOLST forms should be stored in a unique MOLST field or tab that can be accessed instantly, and preferably within one click. The tab can be marked with a yes/no box, so that the provider can see if a form exists before opening the tab. The unique MOLST file within the inpatient and outpatient EMR should only contain MOLST medical orders.

## Next Steps for eMOLST

Currently we are between phases one and two of the eMOLST Community Deployment steps described below.

- *Phase One*—Deploy eMOLST without Rochester RHIO integration.
- *Phase Two*—Deploy eMOLST with Rochester RHIO integration.
- *Phase Three*—Exchange and view eMOLST forms through the Rochester RHIO and integrated systems, including EMS.
- *Phase Four*—Replicate steps one through three with other RHIO Service Areas across New York State.
- *Phase Five*—Leverage New York State's SHIN-NY network of RHIOs to transmit eMOLST forms across the state.

In regard to form creation, validation and generation, eMOLST is the best solution to assist providers in the discussion, documentation of clinical steps and legal requirements under NYSPL. At the end of the process, an electronic DOH-5003 MOLST form and a MOLST Chart Documentation Form for adult and minor patients and OPWDD checklist for individuals with developmental disabilities who lack medical decision-making capacity are created. The inherent quality assurance and interoperability features of eMOLST reduce overall liability and risk. Systems which generate MOLST forms electronically within a third-party system are NOT endorsed and should not be used.



### Why Do eMOLST?

#### Improves Quality Outcomes

- *Safe* – built-in quality controls for correct orders; does not allow for incongruous medical orders
- *Effective* – enables providers to follow clinical steps and meet legal requirements
- *Patient-centered* – goals for care guide choice of interventions
- *Timely* – web-based; assures accessibility across care transitions, including documentation of discussion
- *Efficient* – more time for discussion; less time for documentation, while ensuring accuracy
- *Equitable* – integrates needs of adults, minors, developmentally disabled who lack medical decision-making capacity; can be used in all clinical care settings

#### Improves Legal Outcomes

- Improves compliance with NYS Public Health Law (FHCDA, §1750-b)
- Ensures accurate documentation
- Reduces potential liability
- Reduces potential for DOH deficiencies

#### Improves Provider Satisfaction

- Easy to learn, easy to use
- DOH-approved process for conversion of paper MOLST to eMOLST
- Creates MOLST and MOLST Chart Documentation Form
- Helps providers learn complexities of NYSPHL
- Tracks when “Review and Renewal” is needed
- Opportunity to link eMOLST training and training for enhanced reimbursement model for thoughtful MOLST discussions

#### Provides System-based Solution for Health Systems

- Improves compliance of FHCDA, PCIA, PCAA
- Quality Assurance/Quality Improvement – members can access Analytics
  - Integrates outcome measurement and trend reporting
  - Allows access to aggregate de-identified data analysis
  - Data can be used for Joint Commission Advanced Certification in Palliative Care
- Information Technology
  - Can be used with/without EHR and conversion
  - Web-based solution
- Improve financial outcomes
  - Meets CMS requirements for reimbursement
  - Tracks time spent and elements required for enhanced reimbursement model for thoughtful MOLST discussion

## Endnotes

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3. *Legislation, COMPASSION AND SUPPORT AT THE END OF LIFE*, <http://www.compassionandsupport.org/index.php/legislation> (last visited March 1, 2012).
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6. N.Y. PUB. HEALTH LAW § 2994-d.
7. *Id.*
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9. *Medical Orders for Life-Sustaining Treatment (MOLST)*, N.Y. ST. DEPT OF HEALTH, [http://www.nyhealth.gov/professionals/patients/patient\\_rights/molst/](http://www.nyhealth.gov/professionals/patients/patient_rights/molst/) (last visited March 1, 2012).
10. N.Y. PUB. HEALTH LAW § 2997-c.
11. N.Y. PUB. HEALTH LAW § 2997-d.
12. N.Y. PUB. HEALTH LAW § 2994-a Subdivision 5-a and 17-a.

**Patricia Bomba, MD, FACP, Vice President and Medical Director, Geriatrics, Excellus BlueCross BlueShield** is a nationally recognized advance care planning and palliative care expert who has led development of a two-step approach to advance care planning: *Community Conversations on Compassionate Care and Medical*

*Orders for Life-Sustaining Treatment* program detailed on the community website, [CompassionAndSupport.org](http://CompassionAndSupport.org). Her collaborative work with NYSDOH on health policy and legislative advocacy established MOLST as a state-wide program. Currently, she chairs the MOLST State-wide Implementation Team and the National Healthcare Decisions Day New York State Coalition, serves as the eMOLST Program Director, is New York State's representative on the National POLST Paradigm Task Force, and is a member of the Medical Society of the State of New York Ethics Committee. She is a member of the American Board of Internal Medicine Committee developing the Primary Palliative Care Performance Improvement Module and served as a member of the Review Committee of the National Quality Forum's *Framework and Preferred Practices for a Palliative and Hospice Care Quality* project.

Katie Orem, MPH, is the Geriatrics & Palliative Care Program Manager and eMOLST Administrator at Excellus BlueCross BlueShield. She supports the evaluation and expansion of Geriatric, Palliative Care and End-of-Life Care (EOLC) initiatives internally, across New York State and nationally, through collection of and analysis of outcomes. Katie initially worked at Excellus BlueCross Blue Shield as a Summer College Intern. Subsequently as a Project Analyst in the Geriatrics Department, she supported creation of the HEAL 5 grant that resulted in the eMOLST project with an ultimate goal of creating a New York State registry of advance directives and MOLST forms.

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[ FROM PUBLICATION TO PRACTICE ]

An interdisciplinary look at advancing pain care, education, and research  
**RESPONDING TO THE IOM'S CALL TO ACTION  
TO IMPROVE PAIN MANAGEMENT**

[ FACULTY ]

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[ LEARNING OBJECTIVES ]

After reading this publication, the provider will be able to do the following:

- [ ] List the underlying principles of the Institute of Medicine's (IOM) report, *Relieving Pain in America*.
- [ ] Discuss the recommendations in the blueprint put forth by the IOM to improve pain management.
- [ ] Describe barriers to appropriate pain management in older adults.
- [ ] Identify public-private partnership research opportunities.
- [ ] Discuss knowledge gaps that are appropriate for future study.

**The Institute of Medicine's *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research***

The recently issued report, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*, from the Institute of Medicine (IOM) provides a timely and comprehensive response to the growing public health problem of chronic pain and the challenges of pain management.<sup>1</sup> The report was commissioned by the U.S. Department of Health and Human Services through the National Institutes of Health (NIH) "to increase recognition of pain as a public health problem in the U.S." The study was required by the federal Patient Protection and Affordable Care Act of 2010 to address the widespread problem of undertreated and untreated pain.<sup>2</sup> The IOM was requested to conduct a study to assess the state of the science regarding pain research, care, and education and to make recommendations to advance the field. The report is based on scientific evidence and expert consensus and was reviewed by an independent panel of professionals who brought a breadth of diverse perspectives and technical expertise to the report.

The ultimate conclusions of the report are summed up as follows:

"Pain affects the lives of more than a hundred million Americans, making its control of enormous value to individuals and society. To reduce the impact of pain and the resultant suffering will require a transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain." <sup>1</sup> (p S-4)

**Blueprint for Moving Forward**

*Relieving Pain in America* provides a blueprint for transforming the way pain is understood, assessed, treated, and prevented. The report does not provide clinical recommendations for the diagnosis and treatment of pain. Rather, it describes the scope of the problem of pain from public health and community-based perspectives and provides an overview of needs for care, education, and research. The underlying principles that informed the report are listed in Table 1. The IOM recommendations and objectives for researchers, practitioners,

Developed by  
The Gerontological Society of America



Supported by an educational grant from  
Purdue Pharma L.P.



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## PRE-ACTIVITY QUESTIONS

Assess your baseline knowledge by answering the following questions:

- [ 1 ] According to the Institute of Medicine (IOM), which of the following statements describes a vital issue regarding pain relief?**
  - a ] Chronic pain should be considered a disease in its own right.
  - b ] When opioids are used as prescribed and appropriately monitored, they can be safe and effective.
  - c ] Effective pain management is a moral imperative.
  - d ] All of the above.
- [ 2 ] Which of the following statements about analgesic use in older adults is true?**
  - a ] Most prescription analgesics have been extensively studied in older patients.
  - b ] Older adults with cognitive impairment may have difficulty articulating their pain, creating an important barrier to assessment and treatment.
  - c ] The pharmacokinetics and pharmacodynamics of opioids are unchanged in older adults.
  - d ] Long-term care facility staff receive comprehensive training regarding appropriate analgesic use.
- [ 3 ] The IOM found that pain care for older individuals is generally overseen by which providers?**
  - a ] Cardiologists.
  - b ] Geriatricians.
  - c ] Internal medicine physicians.
  - d ] There often is no one provider overseeing pain care.
- [ 4 ] According to the IOM, which of the following is an important barrier to effective pain management?**
  - a ] Inadequate diffusion of knowledge about pain.
  - b ] Lack of effective analgesics.
  - c ] The small number of patients with severe pain.
  - d ] All of the above.
- [ 5 ] Which of the National Institutes of Health oversees and coordinates pain-related research?**
  - a ] National Cancer Institute.
  - b ] National Institute on Aging.
  - c ] National Institute of General Medicine Sciences.
  - d ] There is no single institute that oversees and coordinates pain-related research.

ANSWER KEY: [ 1 ] d [ 2 ] b [ 3 ] c [ 4 ] d [ 5 ] a

educators, and policy makers to facilitate this transformation are spelled out in the report. Selected steps from the blueprint—including current and emerging opportunities for health care providers and researchers—are highlighted here.

The findings in the report and recommendations in the blueprint are ripe with opportunities to build the capacities of individuals who work with older adults and the communities where they live. From basic research to direct patient care to policy making, strategies to improve pain care and management are suggested.

## Pain as a Public Health Problem

Pain remains widely undertreated in the United States. Unrelieved or poorly managed pain not only results in unnecessary suffering and decreased quality of life, it also has been shown to result in an increased utilization of health care resources, sleep impairment, exacerbations of anxiety and depression, disabilities, and reduced patient satisfaction with the health care system.

The IOM describes what is known about pain as a public health problem and its serious social and economic implications for the nation.<sup>1</sup>

1. Scope and magnitude. Pain affects approximately one-third of Americans and exacts a huge toll from society in terms of morbidity, mortality, disability, demands on the health care system, and economic burden.
2. Disparities in pain management. Although virtually all people experience pain at some point in their lives, there are several vulnerable populations—including older adults—who are more likely to encounter undertreatment of pain.

**EFFECTIVE PAIN MANAGEMENT** is a moral imperative, a professional responsibility, and the duty of people in the healing professions.

3. Population-level response. A comprehensive pain prevention and management strategy is needed for the country.
4. Economic impact. Pain costs the country \$560 billion to \$635 billion annually according to a new conservative estimate developed as part of the IOM study.
5. Diversion and misuse of opioids. The misuse and abuse of opioids raise important societal concerns requiring cross-governmental efforts to ensure that opioids are available for those who need them and not available to abusers.
6. Education of health professionals. Much of the nation's health professions training (including both graduate programs and continuing professional education) is heavily supported by public funds. Resources could be directed for professionals to learn more about the importance of pain prevention, ways to prevent the transition from acute to chronic pain, how to treat pain more effectively in terms of clinical outcomes and costs, and how to prevent physical and psychological comorbidities associated with pain.

## MYTH 1

**Older adults are less sensitive to pain than younger adults.**

**FACT:** Although older adults may have reduced sensitivity to mild painful sensations, they are more vulnerable to the experience of severe pain.

**TABLE 1. UNDERLYING PRINCIPLES ABOUT PAIN AND PAIN MANAGEMENT IN THE IOM REPORT**

Principle	Details
A moral imperative	Effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions.
Chronic pain can be a disease in itself	Chronic pain has a distinct pathology, causing changes through the nervous system that often worsen over time. It has significant psychological and cognitive correlates that can constitute a serious, separate disease entity.
Value of comprehensive treatment	Pain results from a combination of biological, psychological, and social factors and often requires comprehensive approaches to prevention and management.
Need for interdisciplinary approaches	Given chronic pain's diverse effects, interdisciplinary assessment and treatment may produce the best results for people with the most severe and persistent pain problems.
Importance of prevention	Chronic pain has such severe impacts on all aspects of the lives of its sufferers that every effort should be made to achieve both primary prevention (e.g., in surgery for broken hip) and secondary prevention (of the transition from the acute to the chronic state) through early intervention.
Wider use of existing knowledge	While there is much more to be learned about pain and its treatment, even existing knowledge is not always used effectively, and thus substantial numbers of people suffer unnecessarily.
The conundrum of opioids	Diversion and abuse of opioid drugs are serious problems and questions remain about their usefulness long term; however, when opioids are used as prescribed and appropriately monitored, they can be safe and effective, especially for acute, post-operative, and procedural pain, as well as for patients near the end of life who desire more pain relief.
Roles for patients and clinicians	The effectiveness of pain treatments depends greatly on the strength of the clinician-patient relationship; pain treatment is never about the clinician's intervention alone, but about the clinician and patient (and family) working together.
Value of a public health and community-based approach	Many features of the problem of pain lend themselves to public health approaches including a concern about the large number of people affected, disparities in occurrence and treatment, and the goal of prevention. Public health education can help counter the myths, misunderstandings, stereotypes, and stigma that hinder better care.

Source: Reference 1 (p 1-4).





**PAIN COSTS THE COUNTRY** \$560 billion to \$635 billion annually according to a new conservative estimate.

7. Focus on new research. Increasing the national knowledge base on pain can reduce its impact on public health. New knowledge can be generated by the nation's research establishment, through basic, clinical, and translational research, epidemiologic studies, and analysis of care patterns and costs.
8. Infrastructure for addressing the undertreatment of pain. Public health offers an infrastructure and a forum for developing strategies for preventing and addressing pain.

Beyond public health, other sectors of society that must be involved in improving pain management include the health care delivery system, educational institutions and academic medical centers,

businesses and employers, the research establishment, state and federal policy makers, voluntary health organizations, pharmaceutical and device industries, accrediting and licensing bodies, news and information media, and other stakeholders who share the goal of improving pain care.

### Existing Shortfalls in Pain Management

The IOM identifies a range of system, clinician, and patient barriers to improved pain care throughout patients' clinical course of assessment and treatment.

There are numerous ways to assess and treat pain. Pain is often assumed to be a symptom of an underlying condition and while

**THE IOM SUPPORTS** the position that chronic pain is a disease in its own right, not merely a symptom of other conditions.

clinicians may prescribe analgesics, they are often primarily focused on diagnosing and treating the underlying problem. However, if a cause cannot be found, if early treatments fail to bring improvement, and if the pain persists for several months, the pain may become a disease itself. When pain becomes a disease, the patient requires comprehensive assessment, care planning, and treatment. The IOM supports the position that chronic pain is a disease in its own right, not merely a symptom of other conditions. This perspective reframes the management of pain to prevent it from being sidelined while clinicians work to resolve another problem.

### Disparities in Care for Older Adults

The IOM noted several vulnerable subgroups of the U.S. population who are more likely to have chronic pain and endure inadequate treatment. Characteristics that increase the risk of chronic pain include: having English as a second language, race and ethnicity, lower income and education, female gender, children and older adults, geographic location, military veterans, cognitive impairment, surgical patients, cancer patients, and end-of-life patients. Because each of these characteristics increases risk independently, various subgroups of increased risk may exist within already vulnerable subgroups. (For example, older female patients who speak English as a second language may have increased risk compared with older male patients who speak English as their first language.) Additional research could further quantify these disparities.

Substantial evidence shows that pain is undertreated in nursing homes. Research suggests that 45% to 80% of U.S. nursing home residents experience pain that contributes substantially to functional impairment or reduces quality of life.<sup>3-5</sup> Factors that contribute to poor pain management include:

- Cognitively impaired residents' inability to articulate pain and some residents' belief that their pain is untreatable or should be tolerated as part of getting old.
- Insufficient knowledge about pain and ways to reduce it, and lack of training on pain care among health professionals and other staff members working in long-term care settings.
- The lack of standardized tools for assessing and treating pain in nursing homes.
- Concerns about the side effects of medications, especially opioids, in frail individuals and possible adverse interactions with other drugs being taken.

### Pain Care for Older Adults

The report found that while prevalence statistics vary in the general population, increasing severity of pain and pain that interferes with activities are associated with advancing age.<sup>1</sup> Common causes of pain in older adults include joint pain (primarily osteoarthritis), postsurgical pain, and chronic conditions associated with aging, such as shingles. Research indicates that severe pain in older adults leads to a decreased quality of life, including both satisfaction with life and health-related quality of life.<sup>6</sup>

## MYTH 2

**Pain is a natural part of aging.**

**FACT:** Even though pain is associated with several conditions that increase in prevalence with age (e.g., osteoarthritis), pain should never be considered "normal." Pain in older adults can lead to serious consequences including decreased functioning, increased disability, exacerbation of anxiety and depression, increased utilization of health care resources, and decreased quality of life.

## [ MYTH 3 ]

### The management of chronic and acute pain should be similar.

**FACT:** The IOM report concludes that chronic pain is a disease in its own right. Chronic pain has a distinct pathology, causing changes through the nervous system that often worsen over time. It has significant psychological and cognitive correlates that can constitute a serious, separate disease entity. When pain becomes a disease itself, care requires comprehensive assessment, care planning, and treatment.

Treatment of pain in older adults is complicated by a lack of evidence regarding how pharmacokinetic and pharmacodynamic changes that occur with aging affect appropriate dosages of analgesic medications. Older adults generally are excluded from clinical trials of medications, and thus relevant data from this population generally are not collected.

The delivery of effective pain management for older adults begins with an accurate assessment of the patient's pain. However, the experience of pain is influenced by a range of physical, psychosocial, and behavioral factors; and because pain is subjective, accurate assessment is challenging.

Research has found that older individuals have "a modest and somewhat inconsistent age-related decline in pain sensitivity to mild noxious stimuli," which could contribute to underreporting of mild pain symptoms.<sup>7</sup> However, other evidence indicates that the ability to tolerate severe pain decreases with age and that older people are more vulnerable to severe or persistent pain.

#### *Psychosocial Factors and Pain Care*

Psychosocial factors play a central role in the experience of chronic pain. For example, in patients with disabilities, psychosocial factors associated with increased pain include catastrophizing cognitions; task persistence, guarding, and resting coping responses; and perceived social support.<sup>8</sup> Additionally, chronic pain is associated with increased risk for depression and anxiety, which in turn increase the perception of pain leading to a vicious cycle.<sup>9,10</sup> Conversely, there is some evidence that personality, self-efficacy, and religious/spiritual beliefs reduce the impact of chronic pain on patient function.<sup>11–13</sup> Research into various psychosocial factors that are important for chronic pain management in older

adults could lead to improvements in comprehensive pain care.

#### *Relieving Pain and Suffering Among Older Adults: An Issue for Human and Social Services*

Many factors that influence the experience of pain are based on social and economic structures. Due to the complexity of the public health problem of pain, the recommendations of the IOM for comprehensive population-based strategies for pain prevention, treatment, management, and research will require investments in human and social services infrastructures. Such infrastructure investments will need to address, among other important policy goals, geriatric workforce development, health and economic security, and strategies to reduce poverty and improve well-being.

The economic costs of pain are reported based on two primary measures: (1) medical expenditures and (2) lost wages and productivity. However, these measures of economic costs do not take full account of lost social capital resulting from the impact of pain. Creative and productive human agency, human development, and individual and collective action impeded by lack of economic opportunity; inability to access care, social networks, support, or services; and pain and suffering burden are social capital deficits.<sup>14</sup> Attempts to conceptualize or approach measurement of this lost capital presents challenges, especially among vulnerable older persons who in many instances may not be able to communicate effectively about their experiences of pain and its impact in their lives. An important area for future research and investigation is the social service response to the public health problem of pain and utilization of social services by older adults in pain.

Relieving pain and suffering for older adults is a matter of elder justice and



human rights. Ethical consideration of how to allocate scarce resources to improve the health and well-being of older adults will require full public discourse and new research evaluating human and social services interventions and outcomes. The IOM report provides an important foundation for engagement in this discourse and research evaluation process.

### Gaps in Policy that Impede Pain Care

Regulatory and enforcement practices have been found to reduce access to opioid analgesics for people with pain. These practices cause some health care providers to fear being unfairly prosecuted for prescribing opioids.<sup>15</sup> To promote appropriate balance between the need to maintain access to opioids for patients with pain while preventing the misuse, abuse, and diversion of opioids, the IOM recommends focusing on the following barriers:

- Insufficient continuing education and training for health care professionals. Education should address gaps in knowledge and competencies related to pain assessment and management, cultural attitudes about pain, negative and ill-informed attitudes about people with pain, and stereotyping and biases that contribute to disparities in pain care.
- Systematic barriers. These barriers include the magnitude of the pain problem, certain provider attitudes and training, and insurance coverage issues.
- Cultural attitudes of patients. Many patients do not recognize the need to address pain early to minimize progression to chronic pain.
- Geographic barriers. Individuals in rural communities often lack convenient access to care.
- System and organizational barriers. Current reimbursement policies can obstruct patient-centered care. Examples of these barriers

### MYTH 4

**Health care providers receive extensive training in pain management.**

**FACT:** Although pain is the primary reason patients seek medical attention, the majority of health care providers have received minimal training in pain management. The IOM calls for a comprehensive system-wide approach to improving the pain management education that health care providers receive.



## MYTH 5

### Patients are not afraid to ask for pain medication.

**FACT:** Patients with pain are often unaware of their treatment options or may hold inaccurate or value-laden beliefs that obstruct treatment. The IOM report provides a comprehensive list of essential patient education topics that includes reasons why pain relief is important (e.g., poorly managed acute pain can progress to chronic pain) and how patients can learn to advocate for themselves.

are minimal capacity for frequent visits when necessary; limited time for comprehensive assessments; inadequate patient education initiatives; difficulties in accessing specialty care; and lack of reimbursement for needed services.

- Regulatory and legal barriers. The medically appropriate use of opioid analgesics may be inhibited because providers are concerned regarding administrative barriers and overzealous regulatory scrutiny. Some of these barriers may create particular issues for older adults. Older adults often have multiple chronic conditions and visit several physicians. Coordination of care among the patient's providers is often lacking, and no one provider takes the lead to ensure the patient receives adequate pain management. Furthermore, older adults are more likely than others to undergo transitions of care. As patients move from one setting to another, their pain management regimen may not follow them seamlessly due to a number of systematic barriers. For example, if a patient is discharged from the hospital to a long-term care facility, the hospital may prescribe an analgesic that is not on the facility's drug formulary, resulting in treatment delays as the issue is resolved.

The IOM called for population-level strategies to identify and develop a comprehensive approach to overcoming existing barriers to pain care, especially for populations that are disproportionately affected by and undertreated for pain (e.g., older adults). Such an approach can help close the gap between empirical evidence regarding the efficacy of pain treatments and current practice.

### Recommendations for Improving Pain Management

To address the shortcomings noted in the care of patients with pain,

the IOM makes these recommendations:<sup>1</sup> (pp 3-41-3-44)

- Pain care must be individualized for each patient. The majority of care and management should take place through self-management and primary care, with specialty services focused on complex cases. Pain care should be patient-centered and interdisciplinary when necessary. [Older patients often require family involvement to optimize pain care; educational initiatives should account for family and informal caregivers.] Financial, referral, records management, and other systems need to support flexibility for individualized patient care.
- Health care provider organizations should take the lead in developing educational approaches and materials that promote and enable self-management for people with pain and their families. These materials should include information about the nature of pain; ways to use self-help strategies to prevent, cope with, and reduce pain; and the benefits, risks, and costs of various pain management options.
- Collaboration between pain specialists and primary care clinicians should be supported, and patients should be referred to pain centers when appropriate.
- Payers and health care organizations should work to foster coordinated and evidence-based pain care that aligns payment incentives with evidence-based assessment and treatment of pain.
- Health care providers should provide pain assessments that are consistent and complete, and they should document the assessments.

### Education Challenges

Improved education is needed for multiple audiences, including patients and

the general public, to shape demand for appropriate pain care. Patients require better information about their treatment options and require education to correct misperceptions that obstruct optimal treatment. Broad improvements also are needed for health care providers, who often receive little, if any, training in the management of pain, despite the fact that it is the primary complaint of patients presenting to primary care providers.

## Recommendations for Improving Pain Education

The IOM offers the following recommendations to address educational challenges in pain management:<sup>1</sup> (pp 4-26-4-27)

- Education should be utilized as a central part of the necessary cultural transformation of the approach to pain.
- Federal agencies and other stakeholders should expand and redesign their education programs to transform the understanding of pain. Programs should be designed for patients, the public, and health care providers to promote a transformation in their expectations, beliefs, and understanding about pain, its consequences, its management, and its prevention.
- The Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration, accrediting organizations, and undergraduate and graduate health professional training programs should improve pain education curricula for health care professionals.
- Educational programs for medical, dental, nursing, mental health, physical therapy, pharmacy, and other health professionals who participate in the delivery of pain care should increase their capacity to train providers with advanced expertise in pain care.

## Research Challenges

The IOM focused on steps that would be needed to make pain research initiatives a reality with the overall goals of expediting the translation of scientific findings into patient care in tandem with developing new knowledge that will lead to future progress in diagnosis and treatment. Investment is needed in multiple basic science disciplines as well as psychosocial domains.

## Organizing Research Efforts

The array of researchers addressing pain management is spread across multiple disciplines including anesthesiology, physiatry, psychiatry, neurology, occupational medicine, mental health (including psychology and social work), nursing, and palliative care (including palliative social work). The number of actual pain specialists is small and they do not carry the same influence as other large specialty organizations, such as those for heart disease, diabetes, or cancer. Because so many groups are involved in pain management, there is no one overarching group that has ownership. Despite the widespread prevalence of chronic pain, patient advocacy organizations do not have the resources or visibility of patient advocacy organizations for other health conditions.

Pain is a topic of interest for nearly every NIH institute and center. However, because pain management is not on the primary agenda of any individual NIH institute, it is more challenging for researchers to obtain federal funding for projects intended to improve pain management. The NIH Pain Consortium was established to foster collaboration among the NIH institutes and centers. The IOM commends the work of the consortium and believes it should take a more proactive leadership role in transforming how pain research is conducted. The IOM also supports



the development of clinical research networks to conduct randomized controlled trials and other types of clinical research. Such an approach spreads costs across institutes, provides access to larger pools of patients, and achieves other economies of scale.

Significant current pressures to reduce federal expenses will likely prevent the creation of new NIH institutes and will compel existing institutes to focus their spending on their core missions. With federal money for pain research in short supply, efforts to promote public-private partnerships will be important for building and sustaining pain-related research. For example, the Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) is a partnership with the U.S. Food and Drug Administration. The purpose of ACTTION is to identify, prioritize, sponsor, coordinate, and promote innovative activities—with a special interest in optimizing clinical trials—that will expedite the discovery and development of improved analgesic treatments for the benefit of the public health. Other partnerships already exist and could be expanded (see Table 2).

Public-private partnerships allow different organizations to collaborate and leverage their complementary strengths. Numerous potential research targets for such partnerships are enumerated in the IOM report.

Geriatricians who are involved in these research project partnerships can work to ensure that the needs of older individuals are addressed. For example, they can advocate for the inclusion of older subgroups in clinical trials so more data are generated to guide appropriate application of treatment strategies in this vulnerable population. Population-based research could complement controlled trials and effectiveness research by (1) estimating pain prevalence within subgroups of older patients, and (2) building knowledge about the predisposing risk factors of pain the psychosocial consequences of experiencing pain, and the strategies that moderate the impact of pain on everyday outcomes. The IOM report identified several research topic areas that are specific to the concerns of older individuals.

## Recommendations for Research

The IOM report listed several recommendations for improving pain management research:<sup>1</sup> (pp 5-29-5-31)

- The NIH should designate a specific institute to lead efforts in advancing pain research. At the same time, NIH should increase financial resources and staffing support for and broaden the scope of the Pain Consortium and engage higher level staff from the institutes and centers in the consortium's efforts. The Pain Consortium should exert more proactive leadership in effecting the necessary transformation in how pain research is conducted and funded.
- Academia and industry should develop novel agents for the control of pain. Basic and clinical science research is required to discover new classes of pain therapeutics and more efficient ways of developing them.

**TABLE 2. PUBLIC-PRIVATE RESEARCH PARTNERSHIPS**

Organization	Website
Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks	<a href="http://www.acttion.org">www.acttion.org</a>
Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials	<a href="http://www.immpact.org">www.immpact.org</a>
The Mayday Fund	<a href="http://www.painandhealth.org">www.painandhealth.org</a>
NIH Public-Private Partnership Program	<a href="http://ppp.od.nih.gov">http://ppp.od.nih.gov</a>
Patient-Centered Outcomes Research Institute	<a href="http://www.pcori.org">www.pcori.org</a>

## RESOURCES

Agency for Healthcare Research and Quality  
www.ahrq.gov

American Academy of Pain Medicine  
www.painmed.org

American Chronic Pain Association  
www.theacpa.org

American Pain Foundation  
www.painfoundation.org

American Pain Society  
www.ampainsoc.org

Institute of Medicine  
*Relieving Pain in America* (full report)  
www.iom.edu/Reports/2011/Relieving-Pain-in-America-A-Blueprint-for-Transforming-Prevention-Care-Education-Research.aspx

University of Wisconsin  
Pain and Policy Studies Group  
www.painpolicy.wisc.edu

- Federal agencies, such as the NIH, Agency for Healthcare Research and Quality (AHRQ), Centers for Disease Control and Prevention, Department of Defense, and Department of Veterans Affairs, as well as private funders of pain research, should increase support for interdisciplinary research and training on pain-related diseases and deficiencies.
- Public and private funders should increase support for longitudinal research in pain, including comparative effectiveness research and novel randomized controlled trials, to help ensure that patients receive care that works best in both the short and long terms.
- Academic institutes should increase the training of basic, translational, behavioral, population, and clinical pain researchers with the support of training grants from the NIH. Training should recognize the interdisciplinary benefits of research on pain and pain management. Agencies such as the National Center for Health Statistics, the AHRQ, and the CMS should support the training of researchers interested in secondary analysis of pain-related data collected by these agencies.

## Conclusion

The IOM report revealed substantial shortcomings in pain management in the United States and created a blueprint for transforming pain care. Numerous opportunities were identified for individuals who work with older adults to contribute to this transformation. Gerontologists from all disciplines will find compelling issues for this call to action to improve pain management in older adults.

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## POST-ACTIVITY QUESTIONS

*For each question, circle the letter corresponding to the correct answer. There is only one correct answer to each question.*

**[ 1 ] The IOM report provides all of the following, *except*:**

- a ] A blueprint for transforming the way pain is understood, assessed, treated, and prevented.
- b ] Clinical recommendations for the diagnosis and treatment of pain.
- c ] A description of the scope of the problem of pain and an overview of needs for care, education, and research.
- d ] Recommendations and objectives for researchers, practitioners, educators, and policy makers.

**[ 2 ] Which of the following reasons describes how pain is a public health problem in the United States?**

- a ] Pain affects more than a hundred million Americans and places substantial demands on the health care system.
- b ] Public health offers an infrastructure and a form for developing strategies for preventing and addressing pain.
- c ] Vulnerable populations, such as older adults, are more likely to have inadequately treated pain.
- d ] All of the above.

**[ 3 ] According to the IOM's research, the annual cost of pain in the United States is approximately:**

- a ] \$180 billion to \$220 billion.
- b ] \$330 billion to \$395 billion.
- c ] \$560 billion to \$635 billion.
- d ] \$805 billion to \$815 billion.

**[ 4 ] Older individuals may be less sensitive than other adults to:**

- a ] Mild noxious stimuli.
- b ] Severe pain.
- c ] Neuropathic pain.
- d ] Joint pain.

**[ 5 ] Which group should take the lead in developing educational approaches and materials that promote and enable self-management for people with pain?**

- a ] Primary care providers.
- b ] Specialist providers.
- c ] Health care provider organizations.
- d ] The National Institutes of Health.

**[ 6 ] Which of the following statements about analgesic use in older adults is *true*?**

- a ] Most prescription analgesics have been extensively studied in older patients.
- b ] Older adults with cognitive impairment may have difficulty articulating their pain, creating an important barrier to assessment and treatment.
- c ] The pharmacokinetics and pharmacodynamics of opioids are unchanged in older adults.
- d ] Long-term care facility staff receive comprehensive training regarding appropriate analgesic use.

**[ 7 ] Which of the National Institutes of Health oversees and coordinates pain-related research?**

- a ] National Cancer Institute.
- b ] National Institute on Aging.
- c ] National Institute of General Medicine Sciences.
- d ] There is no single institute that oversees and coordinates pain-related research.

**[ 8 ] To better organize pain research efforts, the IOM recommends which of the following actions?**

- a ] Development of clinical research networks to conduct randomized controlled trials.
- b ] Promotion of public-private partnerships.
- c ] Designation of a specific NIH institute to lead efforts to advance pain research and expand the scope of the Pain Consortium.
- d ] All of the above.

**[ 9 ] Which public-private partnership has been specifically developed to expedite discovery and development of improved analgesic treatments?**

- a ] Analgesic Clinical Trial Translations, Innovations, Opportunities, and Networks.
- b ] Mayday Fund.
- c ] NIH Public-Private Partnership.
- d ] Patient-Centered Outcomes Research Institute.

**[ 10 ] Which of the following statements about the management of pain is *false*?**

- a ] Poorly managed acute pain can progress to chronic pain.
- b ] Analgesic regimens usually transfer seamlessly when elders undergo transitions of care.
- c ] Many system barriers are driven by current reimbursement policies.
- d ] The diversion and abuse of opioids, which can be safe and effective when used appropriately, presents a conundrum for pain management.

ANSWER KEY: [ 1 ] b [ 2 ] d [ 3 ] c [ 4 ] a [ 5 ] c [ 6 ] a [ 7 ] c [ 8 ] b [ 9 ] a [ 10 ] b



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## Upcoming Events

- **Fall Section Meeting.** The Executive Committee is in the process of planning a Fall Section Meeting. The meeting will be held on October 26 in Albany, and will address health care reform in New York. Please check the Section's page on the NYSBA website ([www.nysba.org/health](http://www.nysba.org/health)) for more information.

## Recent Events

- ***The Sunshine Act and the Final Rule on Conflicts of Interest in Research.*** This MCLE program, sponsored by the Section, was held on April 4 at Cadwalader, Wickersham & Taft in New York City. Tracy E. Miller of Cadwalader, Wickersham & Taft was program chair. Among the speakers were Ms. Miller, Niall Brennan from CMS, Heather Pierce from the American Association of Medical Colleges and Greg Radinsky from North Shore-LIJ Health System.
- ***Spring Membership Appreciation Reception.*** This event was held at on April 4 at Cadwalader, Wickersham & Taft in New York City, after the Sunshine Act program.
- ***Public Health Law and Public Health Ethics Roundtable.*** On April 21 the Section sponsored a roundtable discussion on Public Health Law and Its Impact on Policy, Hospital Mergers, Palliative Care and Public Health Law Research. The event, which was held at Fordham University, was organized by Mary Beth Morrissey.
- ***Section Chosen as Diversity Champions.*** At NYSBA's May 10, 2012 Section Leaders meeting, the Health Law Section was selected as one of the "Section Diversity Champions."

## Strategic Planning Committee

- Section Chair Francis Serbaroli announced that he has appointed a Strategic Planning Task Force to make recommendations regarding the Section's activities over the next several years. The work of the Strategic Planning Task Force will continue for

about the next two years, and the Task Force's recommendations will be presented to the Executive Committee and then the full Section. Mr. Serbaroli invited anyone interested in working on the Task Force to contact him ([serbarolif@gtlaw.com](mailto:serbarolif@gtlaw.com)) or incoming Section Chair Ellen Weissman ([eweissman@hodgsonruss.com](mailto:eweissman@hodgsonruss.com)).

## Recent Supraspinaus Topics

- New Medicaid Inspector General Supports Less 'Adversarial' Audits—NYTimes.com
- Medical debt load busting budgets—Times Union
- 30 New York-area hospitals hit with poor ratings—New York Daily News
- St. Francis Hospital, Mercy Medical Center win patient safety kudos | Long Island Business News
- Attorney General Seeks Support for Narcotics Prescription Database
- Former Insurance Superintendent James Wrynn Joining Goldberg Segalla
- Study Finds New York Hospitals Flout Charity Rules—NYTimes.com



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Further information about upcoming programs is always available at [www.nysba.org/health](http://www.nysba.org/health). Just click on "Events."

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The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers (listed on page 100) or Committee Chairs for further information about these Committees.

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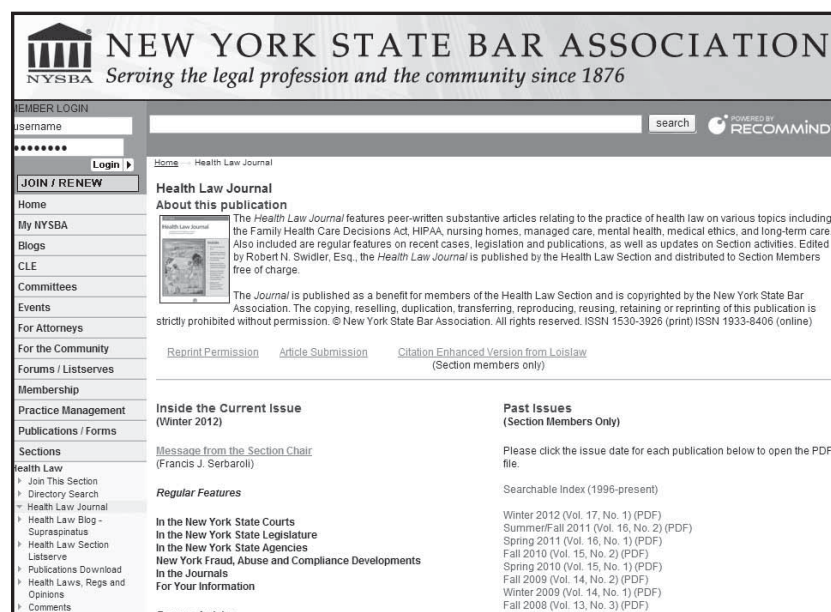
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ISSN 1530-3926 ISSN 1933-8406 (online)

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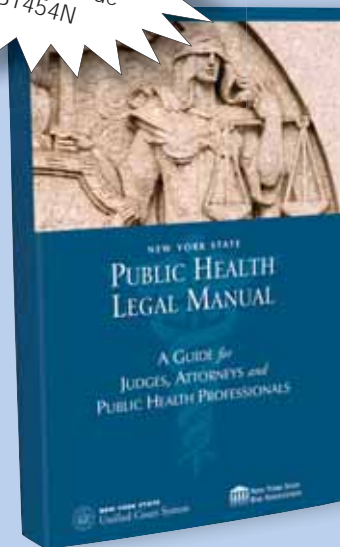
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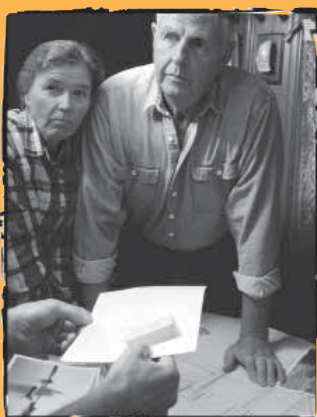
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