

Health Law Journal



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



A SPECIAL EDITION: PUBLIC HEALTH LAW AND VULNERABLE POPULATIONS

Inside

- Framing the Public Health Problem of Maternal Morbidity and Mortality
- Giving NYers a Voice in Oversight of Hospital Consolidation
- Housing Rx: Policy Innovations, Opportunities for Action in NY
- Supervised Injection Facilities: A Collision Between Public Health and Federal, State Law

www.nysba.org/HLS



Health Law Section Annual Meeting 2019



HEALTH LAW JOURNAL

Spring 2019

Vol. 24, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

© 2019 New York State Bar Association

Table of Contents

	Page
Message from the Section Chair	4
<i>Robert Hussar</i>	
Regular Features	
In the New York State Courts	5
<i>Leonard M. Rosenberg</i>	
In the Legislature.....	13
<i>James W. Lytle</i>	
In the New York State Agencies.....	15
<i>Francis J. Serbaroli</i>	
New York State Fraud, Abuse and Compliance Developments	18
<i>Edited by Melissa M. Zambri</i>	
In the Law Journals.....	22
<i>Edited by Cassandra Riva</i>	
For Your Information.....	23
<i>Claudia O. Torrey</i>	
Special Edition: Public Health Law and Vulnerable Populations	
Public Health Law and Vulnerable Populations: An Introduction.....	25
<i>Veda Collmer, Mary Beth Morrissey and Joyce Tichy</i>	
Framing the Public Health Problem of Maternal Morbidity and Mortality: A Social Justice and Moral Imperative.....	27
<i>Anna Burgansky, Camille A. Clare, Karen Bullock, Mary Breda Morrissey, Ivelina V. Popova and Mary Beth Quaranta Morrissey</i>	
Giving New Yorkers a Voice in Oversight of Hospital Consolidation	34
<i>Lois Uttley</i>	
Housing Rx: Policy Innovations and Opportunities for Action in New York State	42
<i>Madeline Morcelle and Leila Barraza</i>	
Health Information Technology and Vulnerable Populations: An Overview of Current Policies.....	46
<i>Veda Collmer</i>	
The Palliative Turn in Person-Centered Care: Public Health and Human Rights-Based Approaches to Interdisciplinary Palliative Care	52
<i>Mary Beth Morrissey, Thomas Caprio and Cary Reid</i>	
Supervised Injection Facilities: A Collision Between Public Health Policy and State and Federal Law	61
<i>Joyce Tichy and Jerry Lynch</i>	
NIFLA and the Future of Health Warnings	67
<i>Thomas Merrill</i>	
Section Matters	
Newsflash: What's Happening in the Section	71
Section Committee and Chairs.....	72

Message from the Chair

Committee activity is the lifeblood of our Section. Our committees perform the real work necessary to make our Section function successfully. Committees also provide an opportunity for members to interact with those who share similar interests and passions. Working on a committee and rolling up your sleeves next to your colleagues is a great way to foster personal and professional relationships.



The wide variety of committees makes it likely that you will find one that comports with your passion and interests. The active Health Law Section committees are:

- Continuing Legal Education
- Diversity Committee
- Ethical Issues in the Provision of Health Care
- E-Health and Information Systems
- Health Care Litigation
- Health Care Providers and In-House Counsel
- Health Professionals
- Legislative Issues
- Long-Term Care
- Medical Research and Biotechnology
- Membership
- Payment, Enforcement and Compliance
- Professional Discipline
- Public Health Law
- Young Lawyers

Our newest committee, the Health Care Litigation Committee, held its inaugural meeting in January, prior to our Section's annual meeting. The enthusiastic response from section members to this committee suggests that it will be an energetic arm of our sections. Members of this committee leverage their knowledge of the highly regulated health care industry in administrative proceedings before state agencies as well as in state and federal courts. They are regularly engaged in litigation between health care providers, government investigations, credentialing proceedings, and disciplinary proceedings, among others. Members share their experiences with ever evolving regulations and standards that are a growing area of concern for health care clients. If you find yourself practicing in DOH, OMIG, MFCU, OPMC or Justice Center proceedings, you may want to consider participating on this committee.

Our committees have become increasingly active over the past couple of years. We continue to explore options to increase participation and communication. I encourage you to participate in one or more committees during the upcoming year. Committee membership is a critical component of our Section's success and will also contribute to your success as a health care attorney. Not only will it be a way for you to develop knowledge in your particular area of interest, it may help you to find and develop a mentor or mentee or other professional relationship for years to come.

Please feel free to contact me or any of the officers with any questions on how to become more involved with any of our committees or other initiatives of our Section.

Best regards,
Bob Hussar
RHussar@barclaydamon.com
(518) 487-8258

NEW YORK STATE BAR ASSOCIATION

Join the Conversation!
Access the Section's Community today.



www.nysba.org/hlscommunity



In the New York State Courts

By Leonard M. Rosenberg

Federal Court Strikes Down New York Opioid Stewardship Act as Unconstitutional

***Healthcare Distribution Alliance v. Zucker*, 2018 WL 6651682 (S.D.N.Y. Dec. 19, 2018)**

Plaintiffs are a national trade association for pharmaceutical wholesale distributors; an association representing manufacturers, distributors, and suppliers in the generic pharmaceuticals industry; and a manufacturer and seller of generic opioid medications. Each of the Plaintiffs brought a lawsuit in the United States District Court, Southern District of New York challenging the constitutionality of the New York Opioid Stewardship Act (OSA). The OSA, which became effective July 1, 2018, seeks to create a \$600 million “stewardship fund” to defray the costs that the state expends in combating opioid addiction. The fund is to be derived from annual assessments on pharmaceutical manufacturers and wholesale distributors licensed to sell or distribute opioid products in New York (collectively, “Licensees”). To ensure that the burden of the assessments does not fall on pharmacies and their customers, the OSA also contains provisions prohibiting Licensees from passing on the cost of the assessments to downstream purchasers.

Each of the Plaintiffs moved for summary judgment, arguing, among other things, that the OSA’s pass-through prohibition violates the Dormant Commerce Clause. Two of the three Plaintiffs also moved for a preliminary injunction. The state cross-moved to dismiss each complaint, arguing that (1) the court is barred from hearing the cases under the Tax Injunction Act; (2) the court should abstain from hearing the cases under the tax comity doctrine; (3) the court should abstain from hearing the cases under the *Pullman* abstention doctrine; (4) the dispute is not ripe for review; and (5) two of the three



Plaintiffs lack standing to bring their claims.

The court first provided an overview of the OSA. The statute imposes six annual assessments in the amount of \$100 mil-

lion, which are to be divided among Licensees based upon their “ratable share” of opioids sold or distributed in New York during the prior calendar year. The New York Department of Health (DOH) is charged with both calculating each Licensee’s ratable share amount and collecting the assessments. The stewardship fund is to be held separately and not comingled with the state’s general fund, and the monies therein would be made available only to support certain state programs related to alcoholism and substance abuse and prescription monitoring. The OSA’s pass-through prohibition provisions subject Licensees to penalties, not to exceed \$1 million per incident, if they pass any portion of their ratable share amount to a purchaser.

The court noted that Plaintiffs offered evidence that the pass-through prohibition could significantly impede the generic opioid market in New York. One of the Plaintiffs indicated that its ratable share payment per unit of opioid medication sold in New York exceeds its average profit margin on that medication. Moreover,

at least one distributor indicated that it would not ship opioid medications to New York unless the manufacturer agreed to pay the ratable share amount. At oral argument, Plaintiffs all declared that the economic impact of the OSA could force them to cease their sales of generic opioids in New York.

The court then addressed the state’s motions to dismiss. First, the court held that the OSA is not a tax for the purposes of the Tax Injunction Act and the tax comity doctrine. The court stated that under Second Circuit precedent a tax must serve general revenue-raising purposes, as determined by the disposition of the funds raised. The court found that the OSA does not meet this standard, as it creates a segregated fund, paid by members of a regulated industry, which is “directed toward specific purposes closely intertwined with the industry in question.” The court also noted that other factors weighed against finding that the OSA is a tax, including that it is collected by the DOH; that the category of persons subject to the assessment were not “defined by general and open-ended criteria,” but were a “specific and defined group”; and that the OSA “studiously avoids the use of the term ‘tax’ throughout its provisions.” Second, the court held that *Pullman* abstention was not appropriate, as it found no plausible reading of the pass-through prohibition provisions that is permissible under the Dormant Commerce Clause. Third, the court held that Plaintiffs’ challenges were ripe for review because the DOH had already sent payment requests to the Licensees, which were

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.

due to be paid on January 1, 2019. Finally, the court rejected the state's argument that two of the Plaintiffs lack standing to challenge the OSA, holding that they both stood to sustain injuries as a result of the statute's pass-through prohibition.

Upon denying the state's motions to dismiss, the court turned to the merits of Plaintiffs' summary judgment motions. The court explained that the Commerce Clause contains an "implicit or 'dormant' limitation on the authority of the states to enact legislation affecting interstate commerce." Such limitation, the court observed, takes two forms: First, a state cannot enact legislation that affects commerce that occurs entirely outside of its territorial borders. Second, a state cannot enact legislation that discriminates against interstate commerce, such as by placing a protective tariff on goods imported from other states. The court held that the OSA's pass-through prohibition provisions, under their most natural reading, violate the Dormant Commerce Clause because they apply broadly to all downstream purchasers and provide no territorial limitation. The court noted that under the plain language of the statute, an out-of-state opioid manufacturer could face a million-dollar penalty for passing its New York surcharge onto pharmacies and opioid users outside of New York. The court then held that if the provisions were read narrowly to apply only to in-state purchasers then they would violate the Dormant Commerce Clause's prohibition on discrimination against interstate commerce. The court stated that such a reading would protect New York opioid purchasers against price increases resulting from the OSA while permitting Licensees to pass off their costs to out-of-state purchasers, which is "antithetical to the idea of intra-national free trade." The court thus held that the OSA's pass-through prohibition could not be applied in a constitutional manner and, as a result, was invalid.

The court then turned to whether the pass-through prohibition provi-

sions were severable from the OSA. The court reviewed the legislative history and observed that the legislature specifically intended for the costs of the OSA to fall on Licensees and not on pharmacies and their customers. As such, the court concluded that the OSA "clearly rests on the twin pillars of a surcharge and a pass-through prohibition," and that with "one pillar knocked out for constitutional reasons, the OSA cannot stand." Because it found that the pass-through prohibition was unconstitutional, the court struck down the statute in its entirety.

Finally, the court granted the motions made by two of the three Plaintiffs for a preliminary injunction. First, the court noted that Plaintiffs were likely to succeed on the merits because it already held that the OSA's pass-through prohibition violates the Dormant Commerce Clause. Second, the court stated that the two moving Plaintiffs presented credible evidence that they would suffer irreparable harm from the state's enforcement of the OSA, as the economic consequences of the statute would cause them to dramatically scale back, or possibly even eliminate, their sales of opioid medications in New York. Third, the court found that a balancing of equities weighed in favor of the injunction, as the state was not permitted to achieve its policy goals through unconstitutional means, and because the OSA could have the unintended consequence of reducing the availability of opioid medications for those who need them.

Appellate Division Holds That Intellectually and Developmentally Disabled Persons Are Not Similarly Situated to Once Competent Persons Such That Disparate Treatment With Regard to End-of-Life Decisions Does Not Violate Equal Protection Rights

***Sloane v. M.G.*, 164 A.D.3d 158, 84 N.Y.S.3d 12 (1st Dep't 2018)**

Petitioner physician made an application for authorization to

withdraw life-sustaining treatment from Respondent, a developmentally disabled patient, in accordance with the decision of Respondent's guardian. On behalf of Respondent, Mental Hygiene Legal Services objected that a meaningful inquiry into the patient's end-of-life wishes should have been conducted, given that Respondent had some capacity to make his own health care decisions prior to his catastrophic illness.

Respondent was an 80-year-old man with a fullscale IQ of 47, who was hospitalized on December 2, 2016. Although he was discharged the next day, on December 5, 2016, Respondent was admitted back to the hospital, having suffered cardiac arrest. He was diagnosed with anoxic brain injury and admitted to the intensive care unit, where he remained in a permanent vegetative state, dependent upon a ventilator, and nonresponsive to verbal or noxious stimuli. Respondent also suffered from multiple failures of the lungs, kidneys and brain. The physicians treating him, including Petitioner, determined that Respondent lacked the capacity to make health care decisions. Petitioner also opined that there was no meaningful hope of recovery, and determined, along with a second physician, that life-sustaining treatment imposed an extraordinary burden on Respondent.

Prior to this hospitalization, Respondent had made health care decisions independently and had lived in a community residence for developmentally disabled individuals. During Respondent's December 2-3, 2016 admission, a "Full Code" order had been entered per Respondent's directive. Although a Full Code order does not address a patient's wishes regarding life-sustaining treatment, if such an order is entered, it is generally presumed that the patient is competent to make health care decisions. Prior to his catastrophic illness on December 5, however, no one at the hospital had spoken with Respondent regarding his preferences as to life-sustaining treatment.

On December 12, 2016, Respondent's guardian expressed her decision to relocate Respondent to hospice care and gradually withdraw life-sustaining treatment pursuant to the Surrogate's Court Procedure Act, SCPA 1750-b, known as the Health Care Decisions Act for Persons with Mental Retardation, sets forth the terms for end-of-life decision-making for individuals with intellectual and developmental disabilities, providing that when it has been determined that a mentally retarded individual lacks the capacity to make health care decisions, including the decision to consent, or refuse to consent, to health care, all such decisions must be based "solely and exclusively on the best interests of the mentally retarded person and, when reasonably known or ascertainable with reasonable diligence, on the mentally retarded person's wishes, including moral and religious beliefs." The statute, enacted in 2002, also sets forth procedures intended to protect the mentally retarded person and prevent improvident decisions by guardians, which procedures must be followed before a guardian's decision to end life-sustaining treatment may be carried out.

MHLS objected to the guardian's determination, and moved to summarily dismiss Petitioner's application to withdraw treatment. MHLS argued that Petitioner should proceed under Article 29-CC of the Public Health Law, rather than SCPA 1750-b, because Respondent previously possessed capacity to request life-sustaining treatment, warranting a meaningful inquiry into his end-of-life wishes, rather than merely a "best interests" analysis. Article 29-CC of the Public Health Law, known as the Family Health Care Decisions Act, enacted in 2010, sets forth the standards for end-of-life decision making for non-disabled individuals. Pursuant to Article 29-CC, a surrogate must make health care decisions "in accordance with the patient's wishes, including the patient's religious and moral beliefs" or "if the patient's wishes are not reasonably known and cannot with reasonable diligence be

ascertained, in accordance with the patient's best interests." The statute also provides that, in all cases, the surrogate's assessment of the patient's wishes and best interests shall be patient-centered, made on an individual basis, and consistent with the patient's values.

MHLS argued that to proceed under SCPA 1750-b rather than Article 29-CC of the Public Health Law would violate Respondent's equal protection rights under both the federal and state constitutions. Petitioner, on the other hand, maintained that the application was properly brought under SCPA 1750-b, as Respondent was in a permanent vegetative state, lacked capacity to make health care decisions, was developmentally disabled, had no advanced directives in place, and had never addressed his end-of-life wishes with his guardian or anyone at his community residence.

MHLS's objection suspended execution of the guardian's decision pending judicial review, pursuant to SCPA 1750-b(5)(a) and (6). Following a hearing that included testimony from several medical professionals who treated Respondent at the hospital, the supreme court, New York County, granted Petitioner's application, authorizing the withdrawal of life-sustaining treatment. The supreme court rejected MHLS's claim that treating Respondent differently from a previously competent, non-disabled person violated his equal protection rights.

The Appellate Division affirmed, holding that, in promulgating SCPA-1750-b, the legislature had not intended to situate intellectually and developmentally disabled persons with previous health care decision-making capabilities similarly to non-disabled persons who were fully competent prior to catastrophic illness.

Although Respondent died within days of termination of his life-sustaining treatment, the court held that an exception to the mootness doctrine applies regarding end-of-life issues. Specifically, the court noted

that, due to the fact that intellectually and developmentally disabled persons have varying capacity, this issue would likely recur and would—absent an exception to the mootness doctrine—evade appellate review given the likelihood of intervening deaths pending appeals involving withdrawal or withholding of life-sustaining treatment.

The court engaged in a detailed analysis of the statutory scheme for persons with intellectual and developmental disabilities, as well as the corresponding statutory scheme applicable to competent persons rendered incompetent by a catastrophic event. Specifically, the court held that competent persons are presumed capable of communicating their wishes regarding end-of-life medical decisions through advance directives, stating their preferences to others or by designating a health care proxy to make decisions for them should they become incompetent. Conversely, the court held that persons whose competence never rose to the level required for informed consent are in a "different legal position" such that any disparity in the treatment of the two groups is rational. The court acknowledged the legislature's policy decision that, although some intellectually and developmentally disabled persons may be higher functioning than others, only mentally competent, non-disabled individuals have full capacity to appreciate the consequences of the decision to end their life, rendering disabled and non-disabled individuals not similarly situated for equal protection purposes.

The court also held that MHLS's equal protection argument "incorrectly assume[d]" that SCPA 1750-b's best interests standard was "entirely separate from and independent from a mentally disabled person's wishes." To this end, the court underscored that while the best interests analysis remains paramount under SCPA 1750-b, the legislature also enumerated factors to be applied in determining best interest, which allow the uniqueness of each disabled person to be taken into account, and require

consideration of the person's wishes, values, interests, and ability to experience and enjoy life. The court held that a guardian should, indeed, examine the patients' subjective preferences in performing his or her obligation to promote the patient's well-being, and that such examination inherently necessitates determination of the patient's functional capacity to understand or deliberate about health care decisions. In so holding, the court emphasized that the reasonableness of a guardian's choice to stop or continue treatment should be evaluated by considering the patient as a whole, and also "so as to assure that intellectually and developmentally disabled persons are provided the right to die with the comfort and dignity that others cherish."

Applying these principles to Respondent, the court held that it was "satisfied" that the Supreme Court's decision was consistent with SCPA 1750-b, given that any medical treatment administered would have provided minimal, if any, benefit, and would only have postponed Respondent's death rather than improve his life. Noting that Respondent's condition was irreversible and that further treatment would be extraordinarily burdensome for him, the court held that Respondent's best interests pursuant to SCPA 1750-b should embrace not only recovery or the avoidance of pain, but also a dignified death.

The court also rejected MHLS's argument that the supreme court made no effort to investigate Respondent's wishes and values more thoroughly before resorting to his perceived best interests. In particular, the court held that there was a lack of evidence regarding what Respondent's desires would have been had he contemplated catastrophic injury, as he had never executed an advance directive, nor was there any evidence that he had expressed any feelings or opinions to anyone regarding life-sustaining treatment.

Court Denies Claims Administrator's Motion to Dismiss Plan Participant's Parity Act Claim for Denial of Mental Health Benefits for Wilderness Therapy

***Gallagher v. Empire HealthChoice Assurance Inc.*, 339 F. Supp. 3d 248 (S.D.N.Y. 2018)**

Plaintiff, plan participant, brought an action against his claims administrator, Empire HealthChoice Assurance Inc. ("Empire"), on behalf of himself and other similarly situated individuals, alleging that Empire's categorical exclusion of mental health benefits for wilderness therapy violated the Mental Health Parity and Addiction Equity Act ("Parity Act"). Plaintiff also sought relief under the Employee Retirement Income Security Act (ERISA) for plan enforcement and breach of fiduciary duty. Empire moved to dismiss and to strike Plaintiff's jury demand. Granting Empire's motion to dismiss in part, the court held that Plaintiff's allegations were sufficient to state a breach of fiduciary duty claim based on Empire's Parity Act violation, but dismissed Plaintiff's plan enforcement claim, holding that Empire was not a proper defendant because it did not have complete discretionary authority to determine benefit claims.

The court first analyzed whether Empire was a proper defendant for purposes of Plaintiff's plan enforcement claim. Prior to the Second Circuit's decision in *New York State Psychiatric Ass'n, Inc. v. UnitedHealth Grp*, 798 F.3d 125 (2d Cir. 2015), the longstanding rule in the Second Circuit was that only a *plan administrator* or trustee could be held liable in a Section 1132(a)(1)(B) action for benefits. Here, the parties concede that Empire is the claims administrator, not the plan administrator, a separate party. In *New York State Psychiatric Ass'n*, the Second Circuit held that, "where the claims administrator had 'sole and absolute discretion' to deny benefits and makes final and binding decisions as to appeals of those denials, the claims administrator exercises

total control over claims for benefits and is an appropriate defendant in a Section 1132(a)(1)(B) action for benefits." The parties disputed whether Empire exercised complete discretion over benefit claims. The court held that Empire did not have "total control" over the determination of benefit claims. While Empire makes an initial determination as to a benefit claim and resolves the first appeal concerning a denial of benefits, the Plan states that Plan participants and beneficiaries "have the right to have [their] Plan Administrator review and reconsider [their] claim" if Empire denies the claim "wholly or partly." Accordingly, the court dismissed Plaintiff's Section 1132(a)(1)(B) claim, concluding that "there is no governing precedent for holding a claims administrator with less than total control responsible."

The court next analyzed whether Plaintiff plausibly pled a violation of the Parity Act. The Parity Act requires group health plans and health insurance issuers to ensure that the financial requirements and treatment limitations applied to mental health benefits be no more restrictive than the predominant financial requirements and treatment limitations applied to substantially all medical and surgical benefits covered by the plan or insurance. Although there is no private right of action under the Parity Act, portions of the law are incorporated into ERISA and may be enforced using ERISA's civil enforcement provisions. To state a Parity Act violation, a plaintiff must allege that (1) the insurance plan is of the type covered by the Parity Act; (2) the insurance plan provides both medical benefits and mental-health benefits; (3) the plan has a treatment limitation—either quantitative or nonquantitative—for one of those benefits that is more restrictive for mental health treatment than it is for medical treatment; and (4) the mental health treatment is in the same classification as the medical treatment to which it is being compared.

Empire contended that Plaintiff did not plead facts to plausibly make

out the third element—that the plan creates a disparity between medical/surgical treatment and mental health/substance abuse treatment. Rejecting Empire’s argument, the court held that, at least at the motion to dismiss stage, the relevant comparison is not whether benefits for wilderness therapy are available for medical/surgical patients, but rather whether the Plan provides benefits for skilled nursing facilities and rehabilitation centers for medical/surgical patients, but denies benefits to those with mental health conditions who seek coverage for a residential treatment center offering wilderness therapy. As Plaintiff alleged that Empire’s “blanket exclusion for services rendered at wilderness treatment centers is a separate treatment limitation applicable only to mental health benefits,” and has identified skilled nursing and rehabilitation facilities as the relevant analogue in the medical/surgical context, the court found Plaintiff’s allegations sufficient to establish the third element of a Parity violation.

Finally, holding that there is no right to a jury trial in a suit brought to recover ERISA benefits, the court granted Empire’s motion to strike the complaint’s jury demand.

Court of Appeals Broadens Justice Center’s Oversight of Provider Agencies

***Anonymous v. Molik*, 32 N.Y.3d 30, 31, 109 N.E.3d 563 (2018)**

Petitioner operates an intermediate health care facility licensed to provide services to people with various cognitive and developmental disabilities. A resident engaged in inappropriate sexual conduct with another resident after two staff members left a common room at Petitioner’s facility. The assault was the third incident in six months. The New York State Justice Center for the Protection of People with Special Needs (the “Justice Center”) investigated the incident, but did not substantiate a report of neglect against the two individuals because “there

were no policies or requirements in place prohibiting staff from leaving the room unattended while residents were gathered there.” However, since the resident had previously engaged in similar conduct, the Justice Center substantiated a concurrent finding of neglect against the Petitioner.

The Petitioner requested that the Justice Center amend its filing to unsubstantiated and to seal it. An administrative law judge denied the request. Petitioner brought an Article 78 proceeding seeking to annul the Justice Center’s determination, contending that Social Services Law § 493 did not authorize the Justice Center to substantiate a finding of neglect against Petitioner. The Third Department unanimously overturned the Justice Center’s concurrent finding. The Court of Appeals reversed.

The Justice Center is an agency empowered to receive, investigate, and respond to allegations of abuse, neglect, or other “reportable incidents” involving disabled residents receiving services in licensed facilities or provider agencies. All reportable incidents must be reported by a facility to the statewide Vulnerable Persons’ Central Register (VPCR). The Justice Center is required to investigate the allegations and submit its findings to the VPCR.

Under Social Services Law § 493(3)(a), the Justice Center’s findings are based on a preponderance of the evidence and indicate:

- (i) the alleged abuse or neglect is substantiated because it is determined that the incident occurred and the subject of the report was responsible or, if no subject can be identified and an incident occurred, that, the facility or provider agency was responsible; or
- (ii) the alleged abuse or neglect is unsubstantiated because it is determined not to have occurred or the subject of the report was not responsible, or because it cannot be determined

that the incident occurred or that the subject of the report was responsible.

Additionally, under Social Services Law § 493(3)(b), the Justice Center can make “a concurrent finding...that a systemic problem caused or contributed to the occurrence of the incident.” The statute also enumerates the various consequences that are triggered in the event of a “substantiated report[] of abuse or neglect.”

Petitioner argued that Social Services Law § 493(3)(a)(i) provides the exclusive grounds for a “substantiated” finding of abuse or neglect. Under the plain language of that provision, the Justice Center’s authority to find neglect against a facility—as opposed to an individual employee—is limited to those incidents where “no [employee] can be identified.” Thus, Petitioner argued that the Justice Center lacked the statutory authority to substantiate a finding of abuse or neglect against a facility where, as here, a subject employee is identified but deemed not personally responsible. Furthermore, since the text of Social Services Law § 493(3) does not specify whether a “concurrent finding,” by itself, authorizes the Justice Center to substantiate a report of abuse or neglect against a facility or provider agency, Petitioner contended that a “concurrent finding” cannot amount to a “substantiated” finding of neglect.

The Court disagreed with the Petitioner and Third Department’s narrow interpretation, which would leave “the Justice Center powerless to address many systemic issues, defeating the purpose of the Act and preventing the Justice Center from protecting vulnerable persons where it is most critical to do so.” In contrast, the Justice Center’s interpretation of the statute would allow for a finding of neglect against a facility wherever “a systemic problem caused or contributed” to an incident regardless of whether the allegations against an individual employee are substantiated. This interpretation would enable the Justice Center to

direct the facility to formulate a plan to fix the systemic problem. The court also noted that the broad construction of the statute also furthers the Justice Center's intended role as the central agency responsible for managing and overseeing the incident reporting system, and for imposing or delegating corrective action.

Federal Court Dismisses False Claims Act Claim Retaliation Claim Against Corporate Defendant's CEO

***United States ex rel. Brumfield v. Narco Freedom, Inc.*, 2018 WL 5817379 (Nov. 2018)**

Plaintiffs brought a lawsuit against defendant Narco Freedom, Inc. and its former CEO, alleging they were fired in violation of a federal False Claims Act (FCA) provision barring retaliation against employees who act lawfully in furtherance of an FCA claim against the employer.

The former CEO, Alan Brand, moved to dismiss under Federal Rules of Civil Procedure 4(m) for improper service, 12(b)(6) for failure to state a claim for which relief can be granted, and that the complaint was time barred under 31 U.S.C. § 3730(h) (3). The court granted Defendant's motion on two of his three arguments, finding that Plaintiffs failed to state a claim for which relief could be granted, and that the complaint was time barred under 31 U.S.C. § 3730(h) (3).

With respect to Brand's improper service argument, the court found that though the amended complaint was never served on him, he was clearly on notice of it, since he had filed multiple motions and multiple attorneys had filed notices of appearance on his behalf. Moreover, the defense of improper service was being raised for the first time nearly two years after the amended complaint was filed. As such, the court held he forfeited this argument.

With respect to his 12(b)(6) argument, Brand argued that a 31 U.S.C. § 3730(h) retaliation claim could not be

brought against him as an individual. Plaintiffs contended that they were bringing the claim against Brand not as an individual, but as an alter ego of their employer, Narco Freedom. The court noted that while the Second Circuit Court of Appeals has not yet addressed the question, "an overwhelming majority of courts... have held that the current version of § 3730(h) does not create a cause of action against supervisors sued in their individual capacities." As such, the court dismissed the § 3730(h) claim against Brand in his individual capacity.

The court acknowledged, however, that whether a § 3730(h) claim could be brought against Brand as an alter ego of an employer corporation was less clear, and that several cases in the Southern and Eastern Districts of New York have suggested that such a claim is viable. Moreover, the court noted federal judges in Washington D.C. have more expressly stated that such a theory is viable. Conversely, the court noted a decision by a judge in the Northern District of Georgia which held that an individual cannot be held liable as an alter ego of their employer corporation. The court, however, decided it did not need to address whether an individual could be liable under § 3730(h) because Plaintiffs failed to allege that Brand was the alter ego of his former employer, Narco Freedom.

In order to reach this decision, the court analyzed New York law on corporations, noting how courts in New York are often reluctant to disregard the corporate entity. The court explained that in order to pierce the corporate veil in New York, a plaintiff is required to show that: (1) the owner exercised complete domination of the corporation in respect to the transaction attacked and (2) such domination was used to commit a fraud or wrong against the plaintiff(s) which resulted in their injury. The court added that there is a list of factors that courts consider when determining whether to pierce the corporate veil, factors such as whether there was: an absence of

formalities that are part and parcel of the corporate existence, adequacy of the corporation's capitalization, use of corporate funds for personal use, overlap in corporate ownership, common office space, address, and phone numbers of corporate entities, business discretion displayed by the allegedly dominated corporation, closeness of the dominated company and related corporation, guarantees of payment of debts of dominated corporation by other corporations, and shared use of property.

However, the court noted that the amended complaint did not contain sufficient factual allegations that Brand dominated Narco Freedom sufficiently to pierce the corporate veil, or that Narco Freedom's corporate form was a fraud or sham. The court took issue with the fact that the complaint merely highlighted Brand's tenure as CEO and that he authorized and instructed others to commit alleged fraud and unlawful retaliation against other employees. Additionally, the court found that a plea allocution taken by Brand, his committing fraud crimes for financial gain, and his operation of Narco without an independent board of directors were not enough to meet the "heavy burden" of establishing that he dominated Narco Freedom or that the corporate form was a sham. Thus, the court dismissed Plaintiff's retaliation claim under 31 U.S.C. § 3730(h).

Next, the court found that the three-year statute of limitations set out in 31 U.S.C. § 3730(h)(3) barred the suit against Brand. The court found that the Plaintiffs did not sufficiently plead a retaliation claim in their original complaint filed in May 2012. The court also found that the original complaint only mentioned damages suffered by the United States, and not the Plaintiffs, who were the victims of the alleged retaliation. As such, according to the court, the bare allegations in the original complaint could not "plausibly" put Brand on notice of a § 3730(h) retaliation claim against him. Because of Brand's lack of notice, the court held that the Plaintiffs' claim in the

amended complaint, filed in June 2016, alleging retaliation against them in December 2011, did not relate back to the original complaint, as the touchstone of relation back under Federal Rule of Civil Procedure 15(c) is notice.

Court Holds Unenforceable Patient's Pre-Operative Agreement Limiting Right to Sue for Medical Malpractice

***Mercado v. Schwarz*, 2019 WL 167050 (Sup. Ct., Suffolk Cty., Jan. 10, 2019)**

Plaintiff, a patient who had undergone surgical procedures, commenced a medical malpractice action against the physician who performed the surgery, his medical practice at the time, and the hospital where the surgery was performed.

Prior to the surgery, plaintiff signed a form, at defendant physician's direction, that limited her ability to bring a malpractice claim in several ways. First, the agreement prohibited the plaintiff from bringing a "meritless" or "frivolous" claim. The determination whether the suit was meritless or frivolous was to be made not by the court in which the claim was brought, but by an unnamed "specialty society affording due process to an expert." Second, if plaintiff sued, the agreement limited her to using an expert witness who was "board certified by the American Board of Medical Specialties in Obstetrics and Gynecology with a subspecialty certification in Gynecologic Oncology." Third, the agreement provided that the parties would have the opportunity to depose each other's experts in advance of trial. The agreement also provided that its breach may cause irreparable harm to the physician's reputation, and would entitle him to seek specific performance and/or injunctive relief.

Plaintiff moved for an order declaring the agreement void and unenforceable, arguing that it was a contract of adhesion, was unconscionable, contravened public policy, was

ambiguous, had been waived, and deprived her of rights conferred by statute. The defendants cross-moved for an order declaring the agreement valid and enforceable, arguing that it is permissible to contractually define how disputes will be resolved, that the agreement was not against public policy, and that the agreement was neither unconscionable nor a contract of adhesion, and its terms had not been waived.

The court found that the agreement was entirely unenforceable. Regarding the restriction on expert witness selection, the court observed that although parties are generally free to dispose of their statutory and constitutional rights by stipulation, "such deference is limited where a question of public policy is involved." Here, the court found that this provision could prevent plaintiff from selecting an otherwise qualified expert for lack of an unrelated certification, and potentially force her to choose from a group of experts who lack experience relevant to her claims. The court also discussed how such a provision, in limiting the pool of potential experts to those with specific qualifications shared by the defendant physician, would increase the chances that defendant and his associates would discourage potential experts from testifying on plaintiff's behalf. Accordingly, the court found that this provision was against public policy, as it conflicted with New York's interests in "the health and welfare of its citizens," the "special relationship between physician and patient," and preventing defendant physicians from deterring other doctors from serving as expert witnesses for plaintiffs, as embodied in CPLR 3101 (d)(1), which permits a party to withhold the expert's name.

Next, the court found that the provision specifying when the parties could depose expert witnesses had been superseded by a stipulation the parties signed at a preliminary conference, in which they agreed to conduct expert disclosure pursuant to CPLR 3101.

Finally, the court found the provision preventing plaintiff from bringing "meritless" claims to be unenforceably vague, ambiguous, and against public policy. Specifically, the court observed that the agreement failed to designate a specific "society" that would evaluate the claim and failed to specify what procedures the "society" would use to make its determination. The court also found the provision to violate public policy, as CPLR 3102-a seeks to address the issue of frivolous malpractice suits by requiring a certificate of merit.

Appellate Division Rules Restrictive Covenant That Effectively Barred Surgeon From Practicing Surgery in New York Metropolitan Area Is Invalid

***Long Island Minimally Invasive Surgery, P.C. v. St. John's Episcopal Hospital*, 164 A.D.3d 575 (2d Dep't 2018)**

Plaintiff, a medical practice specializing in weight-loss surgery, operated out of seven offices throughout the New York metropolitan area and was affiliated with a hospital in Rockville Center. In June 2010, Plaintiff hired Defendant Dr. Javier Andrade to perform weight-loss and other types of surgery pursuant to a three-year employment agreement. The employment agreement contained a restrictive covenant, barring Dr. Andrade from performing any type of surgery for two years within ten miles of any of Plaintiff's seven offices and affiliated hospital(s), (the "restricted zone"). After the three-year term of the employment agreement ended, Dr. Andrade continued to work for Plaintiff until Plaintiff terminated his employment without cause effective April 2014.

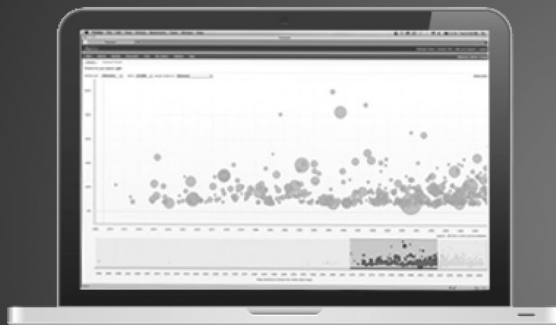
Some five months later, Dr. Andrade accepted a position with Defendant St. John's Episcopal Hospital, a hospital located in the restricted zone. His new office, which was his only office for his new employer, was located outside the restricted zone.

Plaintiff sued Dr. Andrade and his employer, seeking damages and injunctive relief for alleged breach of the restrictive covenant in the employment contract. Dr. Andrade and his employer moved for, *inter alia*, summary judgment dismissal on the grounds that the restrictive covenant was invalid as a matter of law. The Supreme Court of New York, Nassau County granted summary judgment dismissal against them, and Plaintiff appealed.

The Appellate Division affirmed the supreme court's order. The court found, as a threshold matter, that restrictive covenants are not favored and can only be subject to specific enforcement where they are reasonable in time and area, necessary to protect the employer's legitimate interests,

not harmful to the public and not unreasonably burdensome to the employee. The court further found that a restrictive covenant is only reasonable if the restraint (a) is no greater than is required to protect the legitimate interest of the employer, (b) does not impose an undue hardship on the employee, and (c) is not injurious to the public. In this instance, the court held that Defendants made a *prima facie* showing that the restrictive covenant was geographically unreasonable because it effectively barred the doctor from performing his chosen field of medicine, surgery, in the New York metropolitan area. The court further held that Plaintiff failed to raise a triable issue of fact as to whether the broad geographical restriction was necessary to protect its interests.

In addition, the court rejected Plaintiff's argument that the supreme court should have modified the restrictive covenant rather than invalidating it. Citing to *BDO Seidman*, the court explained that partial enforcement of a restrictive covenant may be justified if an employer demonstrates, in addition to a legitimate business interest, an absence of anticompetitive misconduct or coercion. However, the court held Plaintiff failed establish an absence of anticompetitive conduct on its part. Rather, the broadness of the covenant cast doubt on Plaintiff's good faith in imposing it. The court also noted it was undisputed that Plaintiff held a superior bargaining position when Dr. Andrade signed the employment agreement and it had refused to negotiate the covenant.



fastcase[®]
Smarter legal research.
Log in at www.nysba.org



Free to members of the NYSBA.

Members of the New York State Bar Association now have access to Fastcase's New York libraries for free. Unlimited search using Fastcase's smarter legal research tools, unlimited printing, and unlimited reference support, all free to active members of the NYSBA. Log in at www.nysba.org and click the Fastcase logo. And don't forget that Fastcase's free apps for iPhone, Android and iPad connect to your bar account automatically by Mobile Sync. All free as a benefit of membership in the NYSBA.

Turn the page on write-downs and write-offs

In the Legislature

By James W. Lytle

Health care lawyers, along with other New Yorkers, may have been justifiably curious about how the 2019 legislative session would unfold, now that both houses of the legislature and the Governor's mansion were all occupied by Democrats. Would there be an unusually productive and positive legislative process that would enact long-delayed health care-related legislation that would put New York State in the forefront?



Well, it seemed that way at first.

When Governor Andrew Cuomo released his \$175.2 billion executive budget proposal for the 2019-20 fiscal year on January 15, 2019, along with his State of the State address, he outlined an ambitious list of policy priorities for 2019—many of which were enacted in very short order. Those quickly passed policy initiatives included many of his “First 100 Days” proposals (an homage to his predecessor, Franklin Roosevelt), which included the following:

- the Child Victims Act (extending the statute of limitations for child sexual abuse claims);
- the Reproductive Health Act (codifying *Roe v. Wade*);
- the Comprehensive Contraceptive Care Act (enacting in state law and expanding upon the ACA's coverage of contraceptives); and
- the Dream Act (allowing undocumented students access to state financial aid and scholarships for higher education) and
- the so-called “Red Flag” gun control bill (granting law enforcement officials, family members or school officials the

authority to petition to seize the guns of people that pose a danger to themselves or others.)

In addition, as part of his budget proposal, the Governor proposed to legalize adult use of cannabis, a proposal slated to generate \$300 million in revenue by 2021. He also advanced a new middle class tax cut for those with incomes up to \$300,000, a 3.6 percent increase in both education and health spending over last year's funding levels (including an additional \$200 million in spending to combat the opioid epidemic), a climate action plan to reduce greenhouse emissions and a new Maternal Mortality Review Board to undertake a systematic review of New York's maternal deaths, which occur at a higher rate than the national average. While he had advanced a number of Medicaid cost containment proposals—including, most notably, a series of proposals to rein in the growth of the Consumer Directed Personal Assistance Program—the budget seemed otherwise reasonably non-controversial and even included a proposal to establish a commission to examine universal health care—undoubtedly intended to respond to growing support in the Legislature for the New York Health Act, a single payor proposal.

And then reality hit. After the initial budget had been proposed, the Governor and the Comptroller announced that the state was likely to receive \$2.3 billion less in tax revenues than previously projected, on top of the \$500 million less in collections it took in at the end of last year—a shortfall Governor Cuomo attributed to federal tax changes, including the substantial reduction in the deductibility of state and local taxes, which may have prompted high income New Yorkers either to delay tax payments or to avoid them by establishing residency elsewhere.

As a result, after hearings had already been held on most elements of

his initial budget proposal, the Governor submitted budget amendments that would, among other things, authorize the Division of the Budget to implement a plan for reducing appropriations by up to 3 percent if the annual estimate for tax receipts for the fiscal year 2019-20 are reduced by \$500 million or more. The plan would be required to be submitted to the Legislature and the state comptroller before being implemented and if the tax receipt shortfall does not occur by the end of the fiscal year, any reductions made pursuant to the plan must be restored to the affected agencies as soon as possible. The proposal would, in the event of further shortfalls and the failure of the legislature to make other necessary budget changes, allow the budget director to unilaterally reduce certain appropriation authority and disbursements to bring the budget back into balance.

On the Medicaid front, the Governor proposed an across-the-board reduction of all Medicaid payments of \$190 million beginning on April 1, 2019 and then again the following year—reductions that result in \$380 million annual hits to health care plans and providers in each of these next two years with the concomitant loss of the federal share. The payment reductions would reflect a 0.8 percent reduction in payments to providers and health plans but would exempt certain providers, such as federally qualified health centers or hospices, who are protected from these reductions by federal law and certain direct payments authorized under the Mental Hygiene Law.

The Governor also proposed to revamp the hospital indigent care pools, reducing payments to general hospitals (other than major public hospitals) from \$994 million per year to \$719 million per year.

JAMES LYTLE is a partner in the Albany office of Manatt, Phelps & Phillips, LLP.

In addition, the budget amendments would eliminate the Health Care Transformation Fund, which had been created last year with monies from the Fidelis-Centene transaction. The fund was supposed to support health care capital investment, debt retirement or restructuring, housing and other social determinants of health, or transitional operating support to health care providers and was the source of a planned increase of 2 percent in Medicaid hospital rates and 1.5 percent in nursing home rates.

After both houses of the Legislature rejected these massive Medicaid cuts, calculated to approach \$1 billion, including the federal share, even the Governor more or less took them off the table. At the end of the process, \$440 million in Medicaid cuts remained, including reductions in payments to pharmacy benefit managers through the elimination of “spread pricing” and significant reforms of the Consumer Directed Personal Assistance Program (CDPAP) through limits on the numbers of fiscal intermediaries to manage the program and a new reimbursement methodol-

ogy for CDPAP administrative costs, among other cost containment initiatives. The budget also slashed \$59 million in state support for New York City public health programs, just as a measles epidemic reminded New Yorkers of the fragility of public health efforts and otherwise was relatively stingy in advancing new initiatives in the health care arena.


Moreover, even though the across-the-board Medicaid cuts were not included in the budget, the Legislature did provide the Governor with standby authority to cut Medicaid funding by as much as \$190 million (state share) in each of the next two fiscal years—dependent on the success of other cost containment initiatives and the resilience of the state budget’s revenues. The prospect of reviving the Medicaid Redesign Team—which had been convened at the dawn of the Cuomo Administration—has been raised as a means to identify other ways to restrain the growth of the Medicaid program.

Another health care-related proposal included in the budget

amendments would establish a new excise tax on the sale of opioids. Last year’s “Opioid Stewardship Act” had imposed a tax on the sale and distribution of opioids, which was struck down in federal court on interstate commerce grounds. The new tax would apply to a broad spectrum of both natural and synthetic opiate, narcotic and similarly scheduled substances, but would not include buprenorphine, methadone or morphine. To avoid the legal challenges faced by the prior tax, there would be no prohibition on passing the cost of the tax down to pharmacies and hospitals that are dispensing the opioids—which has prompted strong opposition from pharmacies, hospices and other providers.

With the budget now in place, the Legislature will now be turning to a range of proposals that were not enacted as part of the budget, including legalization of adult use of cannabis, an “aid in dying” proposal (endorsed by Governor Cuomo), nurse staffing ratios and single payor legislation or other proposals to expand access to health care. Stay tuned.

NEW YORK STATE BAR ASSOCIATION



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

Brendan Parent

Phone: 212-998-7065

or email:

brendan.parent@nyu.edu

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

REQUEST FOR ARTICLES



In the New York State Agencies

By Francis J. Serbaroli

Controlled Substances

Notice of Emergency Rulemaking. The Department of Health amended section 80.3 of Title 10 N.Y.C.R.R. to reclassify cannabidiol (CBD) from a Schedule I controlled substance to a Schedule V controlled substance. Filed Date: October 30, 2018. Effective Date: October 30, 2018. *See* N.Y. Register November 14, 2018.



Sale of Electronic Cigarette Flavored Liquids

Notice of Withdrawal. The Department of Health withdrew its notice of proposed rulemaking, I.D. No. HLT-45-18- 00006-P. The notice of proposed rulemaking was published in the State Register on November 7, 2018. *See* N.Y. Register November 14, 2018.

Medical Staff — Sepsis Protocols

Notice of Adoption. The Department of Health amended section 405.4 of Title 10 N.Y.C.R.R. to update definitions and guidelines of sepsis and associated protocols for treatment to align with the latest evidence-based practices. File Date: October 26, 2018. Effective Date: November 14, 2018. *See* N.Y. Register November 14, 2018.

Prescription Contraceptive Drugs

Notice of Adoption. The Department of Health amended section 505.3(d) and (e) of Title 18 N.Y.C.R.R. to allow for a written order of prescription contraceptives for family planning purposes to be filled 12 times within one year. File Date: October 26, 2018. Effective Date: November 14, 2018. *See* N.Y. Register November 14, 2018.

Food Service Establishments

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 14 of Title 10 N.Y.C.R.R. to restrict the use of liquid nitrogen and dry ice in food preparation. *See* N.Y. Register November 21, 2018.

Establish Standards for Providers Who Wish to Become Licensed Children's Mental Health Rehabilitation Programs

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 511 of Title 14 N.Y.C.R.R. to provide a vehicle for implementing the new State Plan services. *See* N.Y. Register November 21, 2018.

Early Intervention Program

Notice of Adoption. The Department of Health amended Subpart 69-4 of Title 10 N.Y.C.R.R. to conform existing program regulations to federal regulations and state statute. File Date: November 14, 2018. Effective Date: December 5, 2018. *See* N.Y. Register December 5, 2018.

Update Standards for Adult Homes and Standards for Enriched Housing Programs

Notice of Emergency Rulemaking. The Department of Health amended sections 486.7, 487.4, 488.4, 490.4 and 494.4 of Title 18 N.Y.C.R.R. to prohibit residential providers from excluding an applicant based solely on the individual's status as a wheelchair user. *See* N.Y. Register December 12, 2018.

Criminal History Record Checks and Advanced Home Health Aides

Notice of Emergency Rulemaking. The Department of Health amended Parts 402, 403, 700, 763, 765, 766, 793, 794 and 1001 of Title 10 N.Y.C.R.R. to implement statutory changes related to criminal history records checks and advanced home health aides. *See* N.Y. Register December 12, 2018.

Children's Mental Health Rehabilitation Services

Notice of Withdrawal. The Office of Mental Health withdrew its notice of proposed rulemaking, I.D. No. OMH-47-18- 00003-P from consideration. The notice of proposed rulemaking was published in the State Register on November 21, 2018. *See* N.Y. Register December 12, 2018.

Telehealth

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 635-13 and Part 679 of Title 14 N.Y.C.R.R. to authorize telehealth as a new modality for the delivery of clinical services. File Date: November 26, 2018. Effective Date: December 12, 2018. *See* N.Y. Register December 12, 2018.

Proposed Rule Consolidates and Updates Regulatory Requirements Regarding HIV/AIDS for Patients Admitted to OASAS Programs

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Parts 309, 1070, 1072; and added Part 807 to Title 14 N.Y.C.R.R. to clarify the statutory and regulatory obligations of OASAS programs pertaining to HIV/AIDS.

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

File Date: December 4, 2018. Effective Date: December 19, 2018. *See* N.Y. Register December 19, 2018.

General Provisions

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 800 of Title 14 N.Y.C.R.R. to update provisions consistent with treatment developments; definitions; technical gender language. *See* N.Y. Register December 19, 2018.

Substance Use Disorder Withdrawal and Stabilization Services

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 816; and adding a new Part 816 to Title 14 N.Y.C.R.R. to update provisions consistent with treatment developments; definitions; technical gender language. *See* N.Y. Register December 19, 2018.

Substance Use Disorder Residential Rehabilitation Services for Youth

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 817; and adding a new Part 817 to Title 14 N.Y.C.R.R. to update provisions consistent with treatment developments; definitions; technical gender language. *See* N.Y. Register December 19, 2018.

Substance Use Disorder Inpatient Rehabilitation

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 818; and adding a new Part 818 to Title 14 N.Y.C.R.R. to update provisions consistent with treatment developments; definitions; technical gender language. *See* N.Y. Register December 19, 2018.

Patient Rights

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 815 of Title

14 N.Y.C.R.R. to update provisions consistent with treatment developments; definitions; technical gender language. *See* N.Y. Register December 19, 2018.

General Service Standards for Substance Use Disorder Outpatient Programs

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed repealing Part 822; and adding a new Part 822 to Title 14 N.Y.C.R.R. to update provisions consistent with treatment developments; definitions; technical gender language. *See* N.Y. Register December 19, 2018.

HIV Uninsured Care Programs

Notice of Proposed Rulemaking. The Department of Health proposed amending of Subpart 43-2 of Title 10 N.Y.C.R.R. to amend the HIV Uninsured Care Programs to align program eligibility elements with other health care access programs. *See* N.Y. Register December 19, 2018.

Hospital Policies for Human Trafficking Victims

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 405 and section 751.5 of Title 10 N.Y.C.R.R. to establish policies and procedures for the identification, assessment, treatment, and referral of human trafficking victims. *See* N.Y. Register December 19, 2018.

Nursing Home Weekly Bed Census Survey

Notice of Proposed Rulemaking. The Department of Health proposed adding section 415.32 to Title 10 N.Y.C.R.R. to require nursing homes to electronically submit weekly bed census data to the DOH through the Health Commerce System. *See* N.Y. Register December 19, 2018.

Clinical Laboratory Directors

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 19 of Title 10 N.Y.C.R.R. to recognize additional accrediting boards for qualification of

clinical laboratory directors to obtain a certificate of qualification. *See* N.Y. Register December 19, 2018.

New Requirements for Annual Registration of Licensed Home Care Services Agencies

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 766.9 and 766.12(c) (4) of Title 10 N.Y.C.R.R. to amend the regulations for licensed home care services agencies for the annual registration requirements of the agency. *See* N.Y. Register December 19, 2018.

Eligibility of Services

Notice of Adoption. The Office for People With Developmental Disabilities added Part 629 to Title 14 N.Y.C.R.R. to include eligibility for individuals applying for OPWDD authorized services. File Date: December 4, 2018. Effective Date: December 19, 2018. *See* N.Y. Register December 19, 2018.

Medical Use of Marijuana

Notice of Emergency Rulemaking. The Department of Health amended Section 1004.2 of Title 10 N.Y.C.R.R. to add additional serious conditions for which patients may be certified to use medical marijuana. Filing Date: December 7, 2018. Effective Date: December 7, 2018. *See* N.Y. Register December 26, 2018.

Emergency Medical Services (EMS) Initial Certification Eligibility Requirements

Notice of Adoption. The Department of Health amended sections 800.6 and 800.12 of Title 10 N.Y.C.R.R. to reduce the EMS certification eligibility minimum age from 18 to 17 years of age. File Date: December 24, 2018. Effective Date: January 9, 2019. *See* N.Y. Register January 9, 2019.

Patients' Bill of Rights

Notice of Adoption. The Department of Health amended sections 405.7 and 751.9 of Title 10 N.Y.C.R.R. to require general hospitals and diagnostic and treatment centers to update their statements of patient

rights. File Date: December 18, 2018. Effective Date: January 9, 2019. *See* N.Y. Register January 9, 2019.

Expansion of Telemental Health (Telepsychiatry) Services to Additional OMH-Licensed Settings and Programs

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 596 of Title 14 N.Y.C.R.R. to implement Public Health Law section 2999-dd and address current shortages in psychiatrists and nurse practitioners in psychiatry. *See* N.Y. Register January 23, 2019.

Inpatient Psychiatric Services

Notice of Adoption. The Department of Health amended section 86-1.39 of Title 10 N.Y.C.R.R. to enhance reimbursement mechanisms for inpatient psychiatric services. File Date: January 11, 2019. Effective Date: January 30, 2019. *See* N.Y. Register January 30, 2019.

Statewide Planning and Research Cooperative System (SPARCS)

Notice of Adoption. The Department of Health amended section 400.18 of Title 10 N.Y.C.R.R. to revise the SPARCS regulation related to data intake. File Date: January 11, 2019. Effective Date: January 30, 2019. *See* N.Y. Register January 30, 2019.

Midwifery Birth Center Services

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 69, 400 and 405; and adding Part 795 to Title 10 N.Y.C.R.R. to set the standards for all birth centers to follow the structure of Article 28 requirements. *See* N.Y. Register January 30, 2019.

Medicaid Reimbursement of Nursing Facility Reserved Bed Days for Hospitalizations

Notice of Revised Rulemaking. The Department of Health revised the amendment of section 505.9 of Title 18 N.Y.C.R.R. ; and amendment of section 86-2.40 of Title 10 N.Y.C.R.R. to make changes relating to reserved

bed payments made by Medicaid to nursing facilities. *See* N.Y. Register January 30, 2019.

Telehealth

Notice of Withdrawal. The Office for People With Developmental Disabilities withdrew its notice of proposed rulemaking, I.D. No. PDD-45-18- 00001-EP. The notice of proposed rulemaking was published in the State Register on November 7, 2018. *See* N.Y. Register January 30, 2019.

Update Standards for Adult Homes and Standards for Enriched Housing Programs

Notice of Emergency Rulemaking. The Department of Health amended sections 486.7, 487.4, 488.4, 490.4 and 494.4 of Title 18 N.Y.C.R.R. to prohibit residential providers from excluding an applicant based solely on the individual's status as a wheelchair user. File Date: January 18, 2019. Effective Date: January 18, 2019. *See* N.Y. Register February 6, 2019.

Controlled Substances

Notice of Emergency/Proposed Rulemaking. The Department of Health amended section 80.3 of Title 10 N.Y.C.R.R. to reclassify cannabidiol (CBD) from a Schedule I controlled substance to a Schedule V controlled substance. File Date: January 28, 2019. Effective Date: January 28, 2019. *See* N.Y. Register February 13, 2019.

Newborn Screening for Phenylketonuria and Other Diseases

Notice of Adoption. The Department of Health amended Subpart 69-1 of Title 10 N.Y.C.R.R. to support timely collection and submission of specimens for the detection of diseases in newborn infants in New York State. File Date: January 28, 2019. Effective Date: February 13, 2019. *See* N.Y. Register February 13, 2019.

Charges for Professional Health Services

Notice of Withdrawal. The Department of Financial Services withdrew its notice of proposed rulemak-

ing, I.D. No. DFS-26-18- 00002-EP. The notice of proposed rulemaking was published in the State Register on June 27, 2018. *See* N.Y. Register February 20, 2019.

Charges for Professional Health Services

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 68 (Regulation 83) of Title 11 N.Y.C.R.R. to delay the effective date of the Workers' Compensation fee schedule increases for no-fault reimbursement. *See* N.Y. Register February 20, 2019.

Medical Use of Marijuana

Notice of Emergency Rulemaking. The Department of Health amended section 1004.2 of Title 10 N.Y.C.R.R. to add additional serious conditions for which patients may be certified to use medical marijuana. *See* N.Y. Register February 20, 2019.

Voluntary Foster Care Agency Health Facility Licensure

Notice of Adoption. The Department of Health added Parts 769 and 770 to Title 10 N.Y.C.R.R. to license Voluntary Foster Care Agencies to provide limited health-related services. File Date: February 5, 2019. Effective Date: February 5, 2019. *See* N.Y. Register February 20, 2019.

Establish Standards for Providers Who Wish to Become Licensed Children's Mental Health Rehabilitation Programs

Notice of Proposed Rulemaking. The Office of Mental Health proposed renumbering of Part 511 to Subpart 511-1; and adding Subpart 511-2 to Title 14 N.Y.C.R.R. to establish standards for providers who wish to become licensed Children's Mental Health Rehabilitation programs. *See* N.Y. Register February 20, 2019.

New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health Medicaid Decisions

Compiled by Maggie Surowka Rossi

Pediatric Dental Associates, P.C. and Elan Kaufman, DMD (DOH Decision on Motion January 28, 2019, Jean T. Carney, Administrative Law Judge (ALJ))

The New York State Office of the Medicaid Inspector General (OMIG) requested reargument and reconsideration of ALJ Carney's June 14, 2018 Decision to allow a hearing to go forward. ALJ Carney denied OMIG's motion to reargue as untimely since it was made nearly five months after the June 14, 2018 Decision, well beyond the 30 days allowed under CPLR § 2201(d)(3). As to its motion to renew, ALJ Carney denied that motion as well, finding that OMIG's attempt to submit the Final Audit Report, which it had omitted in its original submission, was improper as it was known at the time of the original submission and OMIG presented no reasonable justification for its prior omission. As such, the provider's request for a hearing was honored as timely.

Tamar Transportation Corp., Aleksandr Berezovskiy and Eduard Borovskoy (DOH Decision after Hearing January 16, 2019, Jean T. Carney, ALJ)

The providers challenged a Notice of Final Agency Action that sought restitution and censure for providing services for a period of time while its license with the Department of Transportation (DOT) was revoked. Tamar Transportation Corp. is an ambulette and transportation provider owned by the individual appellants. The issue in this matter involves the Insurance Company filing Certificates of Liability coverage

with the DOT. The provider showed evidence that there was no lapse in insurance and the insurance company confirmed and noted that it could not submit

proof of insurance because of an issue with the fax number provided. Appellants had no control over whether the certificates were submitted to DOT and contended that they did not receive DOT's Notice of Suspension or Notice of Revocation of its DOT license. The evidence produced by DOT noted that the provider was served the Notice of Revocation by regular mail to the address of the provider. As such, ALJ Carney found that service was effective despite the testimony by appellants that they had not received the notice and that their mail was often received by other tenants in their building. ALJ Carney found that appellants failed to implement adequate internal controls to prevent the incident. Since it is an unacceptable practice to provide services when a DOT license is revoked, even though there was no actual lapse in the liability insurances, OMIG was entitled to reimbursement but only from the date of the revocation to reinstatement. Moreover, despite the fact that appellants had no previous record of such violations and there was no negative impact on Medicaid recipients, the determination to censure appellants was upheld.

DTS, Inc. (DOH Decision December 21, 2018, Matthew C. Hall, ALJ)

The Decision involves the timeliness of a provider's request for a hearing from a Revised Final Audit Report dated July 19, 2018. OMIG requested the decision without hearing and Appellant was given the



opportunity, but failed to submit any documents to be considered. The evidence showed that there was a Final Audit Report on April 16, 2018 that was rescinded by a Revised Final Audit Report dated July 19, 2018. The ALJ found that the time to request a hearing is 60 days from the date of the Final Audit Report and not when it was received. Therefore, the time to request a hearing expired on September 17, 2018, and appellants' request dated September 27, 2018 was untimely.

Grandell Rehabilitation and Nursing Center (DOH Decision December 19, 2018, Natalie J. Bordeaux, ALJ)

OMIG requested a decision on the timeliness of provider's request for a hearing from a Final Agency Action. Appellant failed to submit any argument or evidence relating to the issue. The ALJ found that the Final Audit Report at issue was dated and mailed on April 21, 2017, and received by Appellant on April 24, 2017. Appellant's request for a hearing was sent on June 23, 2017. The ALJ found that the time to request a hearing is 60 days from the date of the Notice of Agency Action and therefore, the time expired on June 20, 2017. Although its letter requesting the hearing was dated June 19, it was not mailed until June 23. The ALJ therefore determined it was untimely.

New York State Attorney General Press Releases

Compiled by Dena DeFazio, Eric Dyer, Jamie Dughi Hogenkamp and Bridget Steele

Former Owner of Medical Supply Company Sentenced to Prison in Medicaid Fraud Scheme—January 9, 2019—A \$1 million Medicaid fraud scheme led to a former medical supply company owner being sentenced

to one-and-one-third to four years in prison. This came months after the former owner pled guilty to three felonies, Health Care Fraud in the First Degree, Grand Larceny in the Second Degree, and Welfare Fraud in the Third Degree. The scheme involved “up-coding” where the former owner would file false claims with Medicaid and a Medicaid-funded Managed Care Organization for dispensing expensive enteral nutrition formula, when the company was actually dispensing Pediasure (an inexpensive supplement) to beneficiaries. The former owner also admitted to illegally obtaining social security numbers and using the numbers to illegally receive welfare benefits. <https://ag.ny.gov/press-release/attorney-general-james-announces-state-prison-sentence-former-owner-brooklyn-medical>.

“Three-Quarter House” Director Convicted of Defrauding Medicaid— January 8, 2019—A former director of a substance use disorder outpatient treatment program and owner of “Three-Quarter Houses” was convicted for his involvement in a kickback scheme worth over \$2 million in fraudulent Medicaid claims. The scheme offered below market rent housing to homeless individuals in “Three-Quarter Houses,” owned by the former director, so long as these same individuals attended treatment at the former director’s outpatient program. If program participants failed to abide by the mandatory treatment requirement, they were evicted from the “Three-Quarter House.” The former director, in turn, received Medicaid payments for treatment provided in the outpatient program. It was determined that the overlap in staff and operations of the “Three-Quarter Houses” and outpatient program made the “Three-Quarter Houses” effectively unlicensed residential treatment programs. The former director and the outpatient program were charged with felonies, Grand Larceny in the First Degree and violating the Social Services Law prohibiting the payment of kickbacks related to the provision of services

Ms. ZAMBRI is the managing partner of the Albany Office of Barclay Damon, LLP and the Co-Chair of the Firm’s Health Care and Human Services Practice Area, focusing her practice on enterprise development and regulatory guidance for the health care industry. She also teaches Legal Aspects of Health Care for Clarkson University and is an Adjunct Professor at Albany Law School.

Ms. ROSSI is Counsel to Barclay Damon, LLP in its Albany Office, focusing her practice on health care law, advising health care providers on federal and state statutory and regulatory compliance, and representing health care providers in response to audits, investigations and disciplinary matters.

Ms. DUGHI is an associate attorney at Barclay Damon, LLP in its Albany Office, focusing her practice on the health care controversies and regulatory matters. Ms. Dughi was formerly a Clerk on the New York Court of Appeals for the Honorable Michael J. Garcia.

Ms. STEELE is an associate attorney at Barclay Damon, LLP in its Buffalo office, focusing her practice on health care law, including assisting organizations with regulatory and compliance matters.

Ms. DEFazio is an associate attorney at Barclay Damon, LLP in its Albany office, focusing her practice in the health care and human services and health care controversies areas, including regulatory and compliance matters, and health care-related litigation and administrative proceedings. Ms. DeFazio also has a M.S.W. from the University at Buffalo.

Mr. DYER is an associate attorney at Barclay Damon, LLP in its Albany office, focusing his practice in the health care and human services area, including compliance and regulatory matters. Mr. Dyer also has an M.B.A. in Health Care Management from Clarkson University.

under the State’s Medicaid program. Separately, the program was charged with three counts of Offering a False Instrument for Filing in the First Degree, a felony, and violating the State’s Mental Hygiene Law prohibiting the operation of a residential treatment program without the proper operating certificate, a misdemeanor. <https://ag.ny.gov/press-release/attorney-general-james-announces-conviction-three-quarter-house-director-charged>

Two Licensed Nurses and The Former Director of a Brooklyn Hospital Convicted for Larceny Scheme— January 8, 2019—As part of a “no show” job scheme at a Brooklyn not-for-profit community-based hospital, two nurses and a hospital employee stole approximately \$750,000 from the hospital. The scheme lasted over five years and was premised on the two nurses submitting falsified timesheets to the former hospital employee to make it appear as if they were working when they were not. For the employee’s assistance, the nurses would pay a kickback. Relatedly, while this scheme was occurring, the nurse that

stole the majority of the money also represented that she had no income and applied for Medicaid, and failed to file personal income taxes. This resulted in \$30,000 of paid false claims through Medicaid and \$40,000 in underpayment of taxes. This nurse pled guilty to felonies, two counts of Grand Larceny in the Third Degree and one count of Criminal Tax Fraud in the Third Degree, and is expected to be sentenced to five months in jail and five years of probation. The other nurse cooperated with the investigation, paid restitution in the amount she stole (\$125,000) and pled guilty to Criminal Facilitation in the Fourth Degree, a misdemeanor, and Petit Larceny, also a misdemeanor. The former employee also cooperated with the investigation and pled guilty to four felonies, Grand Larceny in the Second Degree, Grand Larceny in the Third Degree, Forgery in the Second Degree, Commercial Bribe Receiving in the First Degree, and paid \$200,000 in restitution and is expected to receive five years of probation. <https://ag.ny.gov/press-release/attorney-general-james-announces-criminal->

convictions-two-licensed-nurses-and-former.

Former SUNY Upstate Medical University President Sentenced After He Admitted to Abusing His Position to Illegally Boost His Pay—December 17, 2018—The former President of SUNY Upstate Medical University was sentenced to three years' probation and must pay over \$250,000 in restitution and fines after pleading guilty to three counts of Official Misconduct in September of 2018. The former President admitted to abusing his position by using several methods to illegally increase his pay, without obtaining the necessary approval for raises and increases in compensation. As of the date of his plea, the former President paid \$75,000 toward the amount of the restitution and fines, and must pay the remaining balance over the course of the three years' probation. Moreover, failure to adhere to the terms and conditions of probation, including the payment of restitution, could result in up to three years in jail. <https://ag.ny.gov/press-release/ag-underwood-announces-sentencing-former-suny-upstate-medical-university-president>.

Settlement Reached with EmblemHealth to Ensure Health Insurance Coverage for Gender Reassignment Surgery—December 12, 2018—A settlement was reached with EmblemHealth and New York State requiring it to cover gender reassignment surgery for its members, as well as update its Gender Reassignment Surgery Guidelines, maintain the changes, and continue to update its criteria pursuant to formal reviews. Additionally, EmblemHealth must pay restitution to its members who were improperly denied coverage for gender reassignment surgery, as well as \$250,000 in civil penalties to New York State. The NYS Attorney General's investigation found that (1) EmblemHealth's process for updating its criteria for gender reassignment surgery and its review of member requests were deficient; (2) during the time they remained in effect, its Gender Reassignment Surgery Guidelines were outdated, and neither medi-

cally accurate nor evidence-based; (3) between January 2014 and July 2017, EmblemHealth received 79 requests for pre-authorization of gender reassignment surgical procedures and 22 requests were denied; and (4) it provided misleading and deceptive information to plan members indicating that the Guidelines were based on current clinical information and standard medical guidelines, when they were not. <https://ag.ny.gov/press-release/ag-underwood-announces-settlement-emblemhealth-ensure-health-insurance-coverage-gender>.

Settlements Reached with Seven New York Hospitals to Stop Illegal Billing of Rape Survivors for Forensic Rape Examinations—November 29, 2018—A settlement was reached with seven New York hospitals that illegally billed rape survivors for forensic rape examinations in violation of the New York State Executive Law. Under the agreement, the hospitals must implement written policies to ensure survivors do not receive bills for forensic rape examinations, provide restitution to those improperly billed, and pay costs. The settlement stemmed from a statewide investigation of billing practices in New York hospitals that found at least 200 unlawfully billed forensic rape exams in these seven hospitals, with bills ranging from \$46 to \$3,000 each. <https://ag.ny.gov/press-release/ag-underwood-announces-settlements-7-new-york-hospitals-stop-illegal-billing-rape>.

Clinic Owner, Doctor, and Attorney Arrested for No-Fault Medical Insurance Fraud Scheme—November 15, 2018—In a 61-count indictment, a clinic owner, doctor, and attorney were charged for fraudulently operating a medical clinic in Brooklyn and for participating in an automobile insurance fraud scheme, which included money laundering, grand larceny, and the unauthorized practice of medicine. According to the indictment filed, the defendants allegedly encouraged motor vehicle accident victims to fabricate or exaggerate injuries and paid runners to solicit motor vehicle accident victims,

which allegedly allowed defendants to fraudulently obtain over \$1 million through operation of the clinic. <https://ag.ny.gov/press-release/ag-underwood-announces-arrests-clinic-owner-doctor-and-attorney-no-fault-medical>.

Niagara Falls Taxi Company Owner and Employees Arrested for Allegedly Defrauding Medicaid—November 8, 2018—The owner and four employees of a Niagara Falls taxi company were arrested for submitting claims and receiving payments from Medicaid for taxi rides that were allegedly not provided as claimed. According to the felony complaint, recipients for which the taxi company billed were allegedly never picked up or dropped off or included false address information. <https://ag.ny.gov/press-release/ag-underwood-announces-arrests-niagara-falls-taxi-company-owner-and-employees>.

Suffolk County Doctor Arrested For Lab Testing Scheme—October 30, 2018—A Suffolk County medical doctor was arrested and charged, with his company, with Grand Larceny in the Second Degree. The doctor's laboratory allegedly falsely claimed it rendered certain drug testing services when it had not, performed services that were not medically necessary, and operated without a laboratory director, which is required under state and federal regulations. The Attorney General is claiming the doctor improperly collected approximately \$939,000 from the New York State Medicaid program and New York Medicaid managed care organizations. <https://ag.ny.gov/press-release/ag-underwood-announces-arrest-suffolk-county-doctor-lab-testing-scheme>.

A.G. Underwood Calls on New Yorkers to Help Fight the Opioid Crisis, Bring Unused Prescription Drugs to a Safe Drop-Off Location on National Drug Takeback Day—October 22, 2018—October 27, 2018 was National Prescription Drug Take Back Day and the New York State Attorney General called on New Yorkers to help fight the opioid crisis by heading

to ClearYourCabinet.com, a statewide initiative and website launched this past April, dedicated to helping New Yorkers safely dispose of prescription drugs. As part of the Attorney General's multi-layered approach to tackling the opioid epidemic, the initiative is aimed at helping New Yorkers take one of the simplest steps to prevent addiction by safely disposing of their unused drugs at drop-off sites around New York. <https://ag.ny.gov/press-release/ag-underwood-calls-new-yorkers-help-fight-opioid-crisis-bring-unused-prescription>.

Three Nassau County Nursing Home Staff Convicted for Neglect of 81-Year-Old Ventilator-Dependent Resident—October 16, 2018—Two registered nurses and a certified nurse aide were convicted for neglecting an 81-year-old ventilator-dependent resident of an extended care facility who passed away after becoming disconnected from the ventilator. The jury found all three defendants committed an act of neglect in Willful Violation of Health Laws by failing to provide the resident with timely, consistent, safe, and adequate services, treatment, and care by failing to respond to the alarm signaling the resident was in a life-threatening situation. The certi-

fied nurse aide was also convicted of a felony, Falsifying Business Records in the First Degree, by causing a false entry in the Department of Health Investigation Summary Report. <https://ag.ny.gov/press-release/ag-underwood-announces-convictions-three-nassau-county-nursing-home-staff-neglect-81>.

Transportation Company, President, and Driver Sentenced for Stealing \$1.2 Million from Medicaid—October 16, 2018—A Medicaid medical transportation provider company and its president were sentenced for stealing over \$1.2 million in Medicaid payments for services never rendered and other services provided in direct violation of the rules and regulations. The transportation company pled guilty to Grand Larceny in the Second Degree, a felony, and the company's president pled guilty to Grand Larceny in the Third Degree, also a felony, and was sentenced to three years' conditional discharge and 150 hours of community service. The company was also required to pay a \$10,000 fine, and as a condition of his plea, the president was required to pay \$900,497 in restitution to the state. A taxi driver for the company

was also sentenced for stealing over \$7,500 from the Medicaid program. The driver was sentenced as a Second Felony Offender to two to four years in prison and, as a condition of his plea, was required to pay \$23,598 in restitution to the state. <https://ag.ny.gov/press-release/ag-underwood-announces-sentencing-transportation-company-president-and-driver-stealing>.

New York State Office of the Medicaid Inspector General Update

Compiled by Eric Dyer

OMIG Reminder of Compliance Programs Certification Requirements—December 12, 2018—<https://omig.ny.gov/latest-news/1121-omig-reminder-of-compliance-programs-certification-requirements>.

OMIG Posts Webinar Detailing Updates to the 2018 Compliance Certification Process—November 28, 2018—<https://omig.ny.gov/latest-news/1118-omig-posts-webinar-detailing-updates-to-the-2018-compliance-certification-process>.

NEW YORK STATE BAR ASSOCIATION HEALTH LAW SECTION

VISIT US ONLINE AT
www.nysba.org/HLS



In the Law Journals

Edited by Cassandra Rivaïs

A Decision Aid May Offer Liability Protection for a Bad Obstetrical Outcome: Results of Mock Trials, Suzanne Brodney, Pamela H. Wescott, Benjamin W. Moulton, Katherine Hartmann, Yuchiao Chang, and Michael J. Barry, 46 J. of Law, Med. & Ethics 967 (2019).

An Unintended Consequence of Payment Reforms: Providers Avoiding Nonadherent Patients, Jessica Mantel, 46 J. of Law, Med. & Ethics 931 (2019).

Beyond Balancing: Rethinking the Law of Embryo Disposition, Mary Ziegler, 68 Am. U.L. Rev. 515 (2018).

Beyond Physicians: The Effect of Licensing and Liability Laws on the Supply of Nurse Practitioners and Physician Assistants, Benjamin J. McMichael, 15 J. Empirical Legal Stud. 732 (2018).

Can Outcomes-Based Pharmaceutical Contracts Reduce Drug Prices in the US? A Mixed Methods Assessment, Elizabeth Seeley, Susan Chimonas, and Aaron S. Kesselheim, 46 J. of Law, Med. & Ethics 952 (2019).

Considering the ACA's Impact on Hospital and Physician Consolidation, Lawrence E. Singer, 46 J. of Law, Med. & Ethics 913 (2019).

Controlling Health Care Costs under the ACA — Chaos, Uncertainty, and Transition with CMMI and IPAB, Gwendolyn Roberts Majette, 46 J. of Law, Med. & Ethics 857 (2019).

Cost-Sharing Reductions, Technocrat Tinkering, and Market-Based Health Policy, Allison K. Hoffman, 46 J. of Law, Med. & Ethics 873 (2019).

Deviancy, Dependency, and Disability: The Forgotten History of Eugenics and Mass Incarceration, Laura I. Appleman, 68 Duke L. J. 419 (2018).

Getting More Value from Outcomes-Based Contracts, Nirosha Mahendraratnam and Stacie B. Dusetzina, 46 J. of Law, Med. & Ethics 964 (2019).



Harris and Whole Woman's Health Collide: No Funding Provisions Unduly Burden Reproductive Freedom, Alisha Patton, 70 Hastings L.J. 298 (2018).

Health Care Federalism and Next Steps in Health Reform, Abbe R. Gluck and Nicole Huberfeld, 46 J. of Law, Med. & Ethics 841 (2019).

Health Reform and Theories of Cost Control, Erin C. Fuse Brown, 46 J. of Law, Med. & Ethics 846 (2019).

Is the False Claims Act's First-to-File Rule Jurisdictional?, Scott Glass, 118 Colum. L. Rev. 2361 (2018).

Lactation Law, Meghan Boone, 106 Calif. L. Rev. 1829 (2018).

Medicaid's Role for Children with Special Health Care Needs, MaryBeth Musumeci, 46 J. of Law, Med. & Ethics 897 (2019).

Medicaid, Work, and the Courts: Reigning in HHS Overreach, Sidney D. Watson, 46 J. of Law, Med. & Ethics 887 (2019).

Next Steps in Health Reform: Hospitals, Medicaid Expansion, and Racial Equity, Dayna Bowen Matthew, 46 J. of Law, Med. & Ethics 906 (2019).

"Not in My Name" Claims of Constitutional Right, Abner S. Greene, 98 B.U.L. Rev. 1477 (2018).

No One Owns Data, Lothar Determann, 70 Hastings L. J. 3 (2018).

Payors, Data, and Nudges to Improve Care, Wendy Netter Epstein, 46 J. of Law, Med. & Ethics 927 (2019).

Preparing for the Apocalypse: A Multi-Prong Proposal to Develop Countermeasures for Chemical, Biological, Radiological, and Nuclear Threats, Constance E. Bagley and Anat

Alon-Beck, 40 Cardozo L. Rev. 826 (2018).

Prophylactic Merger Policy, Herbert Hovenkamp, 70 Hastings L.J. 46 (2018).

Public Health and Health Care: Integration, Disintegration, or Eclipse, Peter D. Jacobson and Wendy E. Parmet, 46 J. of Law, Med. & Ethics 940 (2019).

Queering the Welfare State: Paradigmatic Heteronormativity After Obergefell, Matt J. Barnett, 93 N.Y.U.L. Rev. 1634 (2018).

Rape Messaging, Alena Allen, 87 Fordham L. Rev. 1033 (2018).

Regulation and Distribution, Richard L. Revesz, 93 N.Y.U.L. Rev. 1490 (2018).

Regulatory Pathways to Promote Treatment for Substance Use Disorder or Other Under-Treated Conditions Using Risk Adjustment, Matthew J.B. Lawrence, 46 J. of Law, Med. & Ethics 935 (2019).

Responsibility for Epidemics, Matiangai Sirleaf, 97 Tex. L. Rev. 287 (2018).

Retribution in Contract Law, Marco J. Jimenez, 52 U.C. Davis L. Rev. 643 (2018).

Solving the Problem of Criminalizing the Mentally Ill: The Miami Model, C. Joseph Boatwright, 56 Am. Crim. L. Rev. 135 (2019).

The Costs of Clean Water in Hoosick Falls: Private Civil Litigation and the Regulation of Drinking Water Quality, Bronwen B. O'Herin, 93 N.Y.U.L. Rev. 1743 (2018).

The Data Breach Dilemma: Proactive Solutions for Protecting Consumers' Personal Information, Daniel J. Marcus, 68 Duke L. J. 555 (2018).

Continued on page 23

CASSANDRA RIVAÏS is an Associate Attorney at Rivkin Radler, LLP in the Health Services Group.

For Your Information

By Claudia O. Torrey

The following information is a brief overview of some relatively new health information technology initiatives:

Merger Information

On Valentine's Day, "Health Data Answers"¹ published information regarding the merger of two New York State entities: "HealtheConnections" and "HealthlinkNY." Together they will operate under the name "HealtheConnections," with the mission of setting a new standard for regional health improvement. Jointly, the two companies foresee operational efficiencies and increased value for their respective stakeholders, partners, and participants as a single trusted resource.

Both companies are certified by New York State as a Qualified Entity. Before the merger, "HealtheConnections" collaborated with patients, providers, and others in central New York State to provide Health Infor-

mation Exchange (HIE)² services for health care delivery creating better, more cost-efficient care; pre-merger, "HealthlinkNY" provided HIE services in the Hudson Valley, Catskills, and Southern Tier of New York State—services included the promotion of mental health awareness (especially in the workplace), health equity, and public/social determinants of health such as transportation as a barrier to good health. "HealthlinkNY" was also a leader regarding opioid addiction issues.

Post-merger, the new company will serve 26 New York State counties with approximately 4,600 providers in 1,000 locations in the Upper and Lower Hudson Valley, and approximately 4,100 providers in 1,800 locations in Central and Southern regions of New York State.

Proposed Rules

On February 11, 2019, the Office of the National Coordinator (ONC)

for the Health and Human Services Department (HHS) and the Centers for Medicare & Medicaid Services proposed rules to support the use of electronic health information in a secure, seamless fashion.³

Endnotes

1. www.healthdataanswers.net (Feb. 14, 2019).
2. An HIE seeks to bring together the patient health records of those patients with common providers, with the goal of a more complete medical history. The hoped for goals include avoidance of duplicative/unnecessary tests, as well as more informed diagnoses.
3. <https://www.federalregister.gov/public-inspection> (accepting comments until early April), and Department of HHS, Office of the Secretary, 45 CFR Parts 170 and 171 (2019, pp. 1-724), "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program."

CLAUDIA O. TORREY is a Charter Member of the Health Law Section.

In the Law Journals

Continued from page 22

The Future of Health Equity in America: Addressing the Legal and Political Determinants of Health, Daniel E. Dawes, 46 J. of Law, Med. & Ethics 838 (2019).

The Irreplaceable Program in an Era of Uncertainty, Sara Rosenbaum and Elizabeth Taylor, 46 J. of Law, Med. & Ethics 883 (2019).

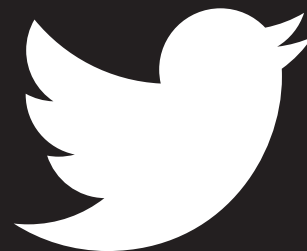
The New Health Care Merger Wave: Does the "Vertical, Good" Maxim Apply?, Thomas L. Greaney, 46 J. of Law, Med. & Ethics 918 (2019).

The Promising Viral Threat to Bacterial Resistance: The Uncertain Patentability of Phage Therapeutics and the Necessity of Alternative Incentives, Kelly Todd, 68 Duke L.J. 768 (2019).

The Puzzle of Inciting Suicide, Guyora Binder and Luis Chiesa, 56 Am. Crim. L. Rev. 65 (2019).

The Role of Direct-Injury Government-Entity Lawsuits in the Opioid Litigation, Edgar Alifirov, 87 Fordham L. Rev. 1141 (2018).

Follow NYSBA
on Twitter



Stay up-to-date on the latest news
from the Association

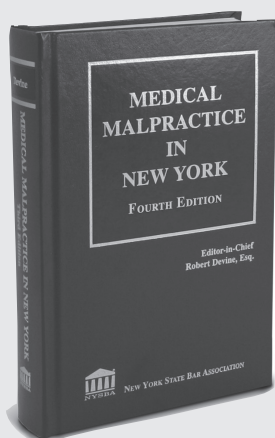
www.twitter.com/nysba

From the NYSBA Book Store

LAW SUIT

Medical Malpractice in New York

Fourth Edition



EDITOR-IN-CHIEF

Robert Devine, Esq.

Bartlett, McDonough & Morahan, LLP,
Mineola, NY

PRODUCT INFO AND PRICES

Print: 41302 | 784 pp. | hardbound
E-Book: 41302E | 784 pp. | PDF

NYSBA Members	\$110
Non-members	\$140

\$5.95 shipping and handling within the continental U.S. The cost for shipping and handling outside the continental U.S. will be based on destination and added to your order. Prices do not include applicable sales tax.

KEY BENEFITS

- Learn from experienced practitioners the many aspects of the trial of a medical malpractice case
- Understand the strategies behind plaintiff and defendant jury selection
- Enhance and perfect your trial practice skills through effective deposition, cross-examination and summation techniques

The fourth edition of *Medical Malpractice in New York* provides you with advanced insight into the many aspects of the trial of a medical malpractice case. Edited by Robert Devine, this book's authors are experienced practitioners who share the knowledge and wisdom they have developed over the years.

This comprehensive title provides a balanced approach to a medical malpractice action. The 32 chapters provide a wealth of knowledge and hundreds of practical tips that can be used by both plaintiff's and defendant's counsel. Although the focus of this book is on medical malpractice actions, many of the chapters are applicable to the trial of any case.

Medical Malpractice in New York, Fourth Edition, includes many forms and other appendices, a thorough table of authorities and a detailed index—making this a necessary addition to your reference library.

Get the Information Edge

1.800.582.2452 www.nysba.org/pubs

Mention Code: PUB9184N



Public Health Law and Vulnerable Populations

By Veda Collmer, Mary Beth Morrissey and
Joyce Tichy

Introduction

This special issue of the New York State Bar Association *Health Law Journal* is devoted to public health law and vulnerable populations. For years, public health officials and public health policy experts have known that health care care and good health do not just happen in the physician's office. Non-medical factors such as race, culture, education, employment, and geography impact health and access to health care. Our most vulnerable populations often experience unstable housing, poverty, and educational or cultural barriers to health literacy.

are often not trained on the non-medical factors affecting health, including race and culture, and therefore cannot identify best practices for addressing these issues. Fortunately, health care is shifting as legislators acknowledge the impact social determinants have on health outcomes, and thus that they are foundational drivers of the unsustainable costs that underlie our current model of health care delivery. Technology, health care expansion, evidence-based practice, and changing payment models will begin to bridge the gap between the physician visit and life outside the clinic. Incorporating these developments into systemic change has proven slow, however, and requires not only policy changes but also challenges to deeply held attitudes and assumptions about vulnerable populations.

"Health care laws are slowly morphing to accommodate new approaches to service delivery. As public health lawyers, our challenge is to educate health care clients and communities on the best approaches for implementing new paths for treating vulnerable populations, while recognizing existing legal barriers."

These non-medical factors, known as social determinants of health, shape an individual's health. Addressing social determinants of health improves access to health care and health outcomes. Alternatively, ignoring social determinants undermines health care delivery and outcomes. In these contexts, we are also called to honor the human rights of all persons to adequate, accessible and affordable health care through policy development and implementation and workforce education and training.

However, treating the social determinants of health is an uphill battle in our current health care industry. For one, traditional health care payment models do not reimburse for addressing social determinants of health. And while payment models are transitioning away from procedures to performance and outcomes, federal and state agencies are still testing the most efficient and cost-effective reimbursement models. Additionally, providers

The articles in this issue address some of the most glaring ways in which the current health care system fails vulnerable populations, and recommend changes to ameliorate these problems. Anna Burgansky, Camille Clare, Karen Bullock, Mary Breda Morrissey, Ivelina Popova and Mary Beth Morrissey describe the racial and cultural underpinnings of higher maternal morbidity and maternal (and infant) mortality rates in the United States and New York State. In an interdisciplinary approach to this serious problem of inequity disproportionately affecting black women, Burgansky and colleagues discuss current initiatives in New York and propose additional policy reforms to improve maternal health outcomes. Lois Uttley's article identifies gaps in the New York State Certificate of Need process, leading to significant downsizing of hospitals and thereby reducing access to care for vulnerable communities. These articles explore how current prac-

tices, policy and case law impede equal access to health care, calling for programmatic and policy changes to mitigate health disparities.

The section on policy issues expands the concept of health care beyond its current blinkered definition in order to incorporate considerations of social determinants of health through use of technology, improving access to housing and expanding the boundaries of care beyond the hospital setting. Authors Madeline Morcelle and Leila Barraza define a policy framework for reclassifying homelessness as a medical condition, thus facilitating treatment planning and reimbursement for addressing housing needs. Veda Collmer's article describes the policy landscape promoting use of health information technology to improve the outcomes of vulnerable populations. Thomas Caprio, Cary Reid and Mary Beth Morrissey address the right to palliative care in the larger context of the relationship of health to human rights, as well as significant changes occurring in delivery systems to help improve access to palliative care and meet the needs of diverse populations. In each of these articles, the authors explore ways existing policy can be utilized to incorporate social determinants into the traditional health care visit, as well as educate providers on ways to address the unique needs of vulnerable individuals.

The section on health warnings and safe injection facilities recognizes the constitutional and legal barriers

of our current health care system as providers seek to implement evidence-based care. Joyce Tichy and Jerry Lynch's persuasive article argues that the evidence supports safe injection facilities as an effective harm reduction strategy for reducing opioid-related deaths, but that the legacy of laws that classify drug addiction as a crime rather than a health disorder hinder the achievement of this public health goal. Authors Tichy and Lynch present potential legal challenges to such facilities, as well as define legislative avenues for establishing safe injection sites. Tom Merrill calls attention to constitutional barriers for implementing health warnings for vulnerable pregnant women. In this article, Merrill identifies commercial speech challenges to providing pregnant women with a range of health care options. These articles recognize that while the health care paradigm is shifting to more efficacious, evidence-based service delivery, outmoded laws continue to act as a barrier to progress.

Health care laws are slowly morphing to accommodate new approaches to service delivery. As public health lawyers, our challenge is to educate health care clients and communities on the best approaches for implementing new paths for treating vulnerable populations, while recognizing existing legal barriers. We must also be willing to advocate for policy changes that will address gaps in law and policy and increase equitable access to care across diverse populations and communities.

MARY BETH QUARANTA MORRISSEY, PhD, MPH, J.D., is a New York health care attorney and a gerontological health and social work researcher. She holds the appointments of Fellow at Fordham University's Global Healthcare Innovation Management Center, and Senior Policy Advisor in Health and Ethics and Aging & Health Workforce Development Institute Director, Finger Lakes Geriatric Education Center, University of Rochester Medical Center. Dr. Morrissey is President of the American Psychological Association Society for Theoretical and Philosophical Psychology; President of the National Committee for the Prevention of Elder Abuse; President of the Collaborative for Palliative Care, New York; Chair of the Westchester County Bar Association Health Law Committee, and past Chair of the Women's Bar Association of the State of New York Health Law and Reproductive Rights Committee. She is a member of the New York State Bar Association Health Law Section, Ethical Issues Committee and Public Health Committee, and past president of the State Society on Aging of New York and the Public Health Association of New York City.

JOYCE TICHY is a health care attorney who has served as the General Counsel for two community hospital systems and a company dedicated to care coordination for individuals with serious mental illness and chronic conditions, and who also served as in house counsel for a large health insurer. Joyce's practice areas include hospital law, health law contracting, health care regulation, health IT law, mergers and acquisitions of health entities, and the rights of mentally ill patients. Joyce is a member of the New York State Bar Association Health Law Section's Public Health Committee and Committee on Medical Research and Biotechnology, the Connecticut Bar Association Health Law Section and Elder Law Section, and the American Health Lawyers Association, and is past Secretary and Chair of the New York City Bar Association Health Law Committee.

VEDA COLLMER is the in-house counsel and Chief Compliance Officer at WebPT, a leading provider in health information technology (HIT) medical record software for the rehabilitation therapist. Veda's practice areas focus on regulatory and compliance matters, including HIPAA, HITECH and other health care IT issues, anti-kickback/fraud and abuse, and compliance with state privacy and data security laws and regulations. Veda received the Robert Wood Johnson Foundation Public Health Law Fellowship in 2012 and completed her fellowship at Arizona State University's Sandra Day O'Connor College of Law. Prior to earning her law degree, Veda was an occupational therapist, providing rehabilitation services in various health care settings.

Framing the Public Health Problem of Maternal Morbidity and Mortality: A Social Justice and Moral Imperative

By Anna Burgansky, Camille A. Clare, Karen Bullock, Mary Breda Morrissey, Ivelina V. Popova, and Mary Beth Quaranta Morrissey

I. Introduction

There is growing attention to the problem of maternal morbidity and mortality, both in New York State and New York City, and in the United States. Given the seriousness and magnitude of this problem for society and its public health significance, we call attention first to the critical importance of this change in policy focus, and importantly, to the need to assure that maternal morbidity and mortality will continue to be a public health policy priority. In this special issue on public health, we turn to the shifting paradigm that is emerging in addressing the nature and extent of the problem. While the dominant biomedical paradigm has no doubt shaped early understanding of maternal morbidity and mortality, the expansion of the medical frame to include diverse inter- and transdisciplinary perspectives, as reflected in the authorship of this article, is promising. The most current research and critical analyses focus more sharply on the public health, ecological, social, and cultural dimensions of the problem as they continue to affect black women and their families and communities. This evolving paradigm shift will help to inform and guide the shaping of a blueprint for more effective policy advocacy in the next decades. There are legal and ethical dimensions of maternal morbidity and mortality and it behooves the disciplines of law and public health to be at the forefront of understanding and addressing this human rights conundrum. The members of the legal community, in collaboration with other professionals in this space, will play a critical role in supporting advocacy for radical policy change.

II. Framing the Public Health Problem: Race and Culture

In 2002, the Institute of Medicine (IOM) issued a report on “Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care.”¹ For the next decade there was a proliferation of studies examining the association between race, culture and poor health outcomes, in search of risk factors and explanatory data that would lead to the elimination of such health disparities across racial groups.^{1,2,3,4} Some research scholars argue that these persistent gaps in the rates of maternal morbidity and mortality (and infant mortality), between black and white women, stem from the inability to reconcile the intricate connection between race and culture in public health

outcomes. There are some basic factors that support the persistence of racialized health care disparities and those include, but are not limited to, failure to honor patient preferences, unfair and inequitable access to health care systems,^{2,3,5} as well as institutionalized racism.^{6,7}

Race and culture are central to an adequate understanding of the complexities of maternal morbidity and mortality. Interdisciplinary (and interprofessional) health care is a field of practice that is evolving with much agreement across disciplines and professions concerning the priority of cultural competence as a standard of care.^{4,8,9,10} Moreover, the problem of racial disparities in both access to and utilization of care during pregnancy and childbirth is a public health crisis. The perpetuation of the high incidence and prevalence of maternal morbidity^{3,4,5} and mortality among black women^{6,9} calls for policy and practice innovations. For example, while there are many risk factors that contribute to infant mortality, what has been reported as unique to black women is the degree to which parental stress is often the culprit, accounting for a large percentage of infant deaths in the United States.³

For many women, factors that influence their retrospective attitudes about the childbirth experience include their sense of control either internally or externally, decision making processes, social support and the efficacy of pain control.¹¹ However, black mothers, in particular, are significantly more likely than mothers of other racial groups to feel they do not have control over the decisions they face while pregnant, including the birthing process. They often feel coerced into accepting unnecessary procedures such as epidurals, episiotomies or passive delivery options, which may include lying on their backs or even cesarean delivery.³ Such sources of chronic stress have been proven to influence adverse birth outcomes.⁵

Researchers have quantified the problem by gathering data, confirming the incidence of deaths among black women in the United States, during or after childbirth.¹² Such studies yield evidence showing that black women are three to four times more likely than white women to die during this life event.¹² According to the Centers for Disease Control and Prevention (CDC) in a 2016 report, black women in the United States experience a maternal mortality rate of 44 deaths per 100,000 live births while for white women the mortality rate is 13 deaths per

100,000 live births.¹² In a mixed methods exploration study conducted by a nonprofit organization, aimed at understanding some of the factors that influence such outcomes,⁹ self-reports of community-dwelling women showed that the problem is systemic, and that the root causes may be social inequities endemic to the lives of black people, specifically, and racial minority groups, generally.^{4,5}

There is evidence that the longstanding history of racism and lack of cultural competence may have a negative impact on childbirth.^{4,6} Mistrust of health care systems that denied black people access in the past is still present in the minds, hearts and souls of black people.^{13,14} Lifelong experiences teach black women to anticipate that race, ethnicity and socioeconomic status are, regrettably, important factors in determining worse outcomes in life expectancy, the likelihood of poverty,¹³ and access to health care. In a qualitative study designed to develop measures of racism for birth outcomes, black women in the United States described their own experiences with internalized concerns about future events based on the experiences of friends and others close to them.⁴ The stress and anxiety associated with racism and childbirth have significant negative implications for birth outcomes.¹⁵ The workplaces of black women produce environmental toxins that create physical, mental and emotional stressors, including racism and discrimination, at a rate higher than other women.³ For all women, socioeconomic status and education level are directly correlated with improved birth outcomes, and thus, women and families with greater educational attainment and/or higher incomes, experience lower rates of low birth weight and infant mortality, except for black women. This social phenomenon has only been explained by theories of racism and discrimination frameworks.^{3,6,13,15} The experience of unequal treatment reminds us to prioritize professional ethics, responsibility, and the commitment to continuing education and training for skills development and responsibility. Research shows that black patients do receive substandard medical care.⁶ Racism is institutionalized and discrimination widespread.¹⁵ In designing our health care programs, we must ensure that providers are culturally competent by setting skilled-based standards, reinforced by education and training to enhance cross-cultural knowledge and awareness and reduce or eliminate health disparities in our care settings and beyond.^{1,9,10} While current research does not indicate a positive relationship between cultural competency training and patient outcomes, more resources for high quality research are needed.¹⁶

Culture influences the contexts of what we do every day, how we behave, speak, relate to others and make sense of the world. Understanding one's self is fundamental to understanding how to relate to others. A step

in developing cultural competence is acknowledging that differences in expectations may exist between oneself and a woman seeking care. Moreover, some outcomes cannot be explained by income or access. Therefore, strategies for assessing one's own implicit biases and prejudices are important in setting goals with persons seeking care from the health systems.

III. Maternal Morbidity and Mortality Data Trends

While maternal death represents the most tragic and devastating event in obstetrical practice, it is often thought of as the "tip of the iceberg," compared to many more cases of severe life-threatening pregnancy-related complications, known as near-misses or maternal morbidities. Severe maternal morbidity (SMM) is described as the unintended outcomes of the process of labor and delivery that result in significant short-term or long-term consequences to a woman's health.¹⁷ SMM, such as hemorrhage, blood transfusion, embolism, severe infection or acute organ failure requiring ICU admission, is 50-100 times more common than maternal mortality, and accounts for an increased risk of death.^{18,19}

Significant racial and ethnic disparities exist in the indicators of maternal morbidity. A review of a database from seven states demonstrated that non-Hispanic black women had the highest rates of SMM, compared to other racial and ethnic groups. Overall, the SMM rate in non-Hispanic black women was 2.5 times higher compared to non-Hispanic white women.²⁰ A recent review of a national dataset, specifically focused on women who experienced post-partum hemorrhage, showed that non-Hispanic black women were at 28% higher risk for severe morbidity and at five times higher risk of death compared to non-Hispanic white women.²¹

Even though non-Hispanic black women make up one-fifth of the live births in New York City, they have the highest SMM rate, that is, in one-third of these births. More specifically, a review of data in New York City from 2008-2012 showed that non-Hispanic black women have the highest SMM rate; that is, 386.9 per 10,000 deliveries. This comprises 35.6 percent of the cases of SMM relative to 21.1 percent of live births. For white, non-Latina women, the SMM rate is 126.7 per 10,000 deliveries. The latter comprises 16.8 percent of cases relative to 30.4 percent of live births for white, non-Latina women. The SMM rate is also high for Puerto Rican women (272.0 per 10,000 deliveries), or women of other Latina origin (248.5 per 10,000 deliveries). Furthermore, women with an underlying chronic condition, such as hypertension, diabetes or heart disease, are three times as likely to have SMM as women with no chronic conditions. Contributing factors that disproportionately affect black women and also increase

the SMM rate include the following: pre-conception health status, obesity and other related co-morbidities, access to care, inadequate housing, residential segregation, lower educational attainment, and racism and its attendant stresses. Most research has focused on black-white disparities, but other demographic groups, such as immigrants, have similar poor maternal outcomes.²²

In the last decade, hemorrhage, hypertensive disorders of pregnancy and thromboembolism were the leading causes of pregnancy-related deaths; these are considered to be most potentially preventable complications.²³ However, more recent data show that maternal deaths related to infection (sepsis), cardiovascular and other chronic medical conditions are on the rise and are among the top reasons for maternal mortality. These trends are not surprising, as more women in the United States delay childbearing and conceive at a later age. Also, increasing proportions of pregnant women are obese and/or have pre-existing medical conditions, such as diabetes, hypertension and heart disease.^{24,25}

In New York State, 42 percent of pregnancy-related deaths were of black mothers. A pregnancy-related death is defined as a death of a woman during pregnancy or within one year from a termination of pregnancy directly caused or exacerbated by the pregnancy.²² From 2012-2013, the New York State Maternal Mortality Review Board identified 62 pregnancy-related and 104 pregnancy-associated deaths. A pregnancy-associated death is defined as the death of a woman, from any cause, while she is pregnant or within one year of the termination of pregnancy.²²

Turning to the U.S. picture, according to a retrospective, observational study of the CDC Health Statistics database and Detailed Mortality Cause of Death database, the United States has had increases in its maternal mortality ratio (MMR) since 2005; that is, 15 per 100,000 live births in 2005 and 21-22 per 100,000 live births in 2013 and 2014, respectively.²⁶ In Canada, the MMR is 10 per 100,000 live births, which is less than half of that in the United States. MMR is the number of maternal deaths per 100,000 live births.²⁶ There has been a significant correlation between the state mortality ranking and the percentage of the non-Hispanic, black women delivery population. Cesarean deliveries, unintended pregnancies, unmarried status, percentage of deliveries to non-Hispanic, black women, and four or fewer prenatal visits are significantly associated with the maternal mortality ratio ($p < 0.05$). Although this is not causative, the weak correlation between cesarean delivery and maternal deaths may be due to the underlying complications of the pregnancy that resulted in the cesarean section itself, and not from complications of the operation.²⁶

There is no statistical correlation between state-specific maternal mortality and either rural status or poverty. There have been demonstrated lower mortality rates in Hispanic women, which might be due to a large immigrant population with unique support systems and family support. Some authors have found that the wide variation in the state maternal mortality ratio is related to social and not medical or geographic factors, such as unintended pregnancies, unmarried status, and non-Hispanic, black race. Certain states with low MMR (such as California, Massachusetts, Nevada, Connecticut, and Colorado)²⁷ may reflect a state-specific excellence in quality, leadership, organization and funding for obstetric care.²⁶

Many prior studies on racial/ethnic disparities in obstetrics have attributed differences in outcomes to social and biologic/genetic factors, but this has not been borne out by data.²⁶ Several recent publications have examined the relationship of socioeconomic factors to racial and ethnic discrepancies in maternal and neonatal morbidities. A study of 2.2 million women concluded that higher education was not protective, and that college-educated non-Hispanic black women had 28 percent higher risk of adverse outcomes compared to similarly educated non-Hispanic white women.²⁸ Another study from 25 hospitals has also demonstrated higher rates of adverse outcomes in non-Hispanic black women, independent of their demographic characteristics or the delivery hospital.²⁹ Similarly, a review of data in New York City showed that college-educated, non-Hispanic black women were 2.6 times more likely to experience severe maternal morbidity compared to college-educated white women.²²

IV. A Call for Action: Clinical Guidelines, Best Practices, Systems of Care and Institutional Change

Disparities in health care may involve complexities across multiple ecosystems in which mothers, providers and health care systems interact. Recent national and local efforts have focused on reducing maternal morbidity and mortality related to preventable causes by improving identification and standardizing the management of these conditions.

Currently, maternal mortality data are collected, stored, and shared via several federal, state, and local sources including but not limited to the CDC, state health departments, and private health care systems.³⁰ The CDC uses its Pregnancy Mortality Surveillance System (PMSS) to collect and code data regarding pregnancy-related deaths and associated risk factors from 50 states, New York City, and Washington, D.C. However, there are a number of problems that exist, including but not limited to: reporting from jurisdictions is not mandatory, the data must be complete at the state level to feed into the

national system, and the use of the data is limited due to confidentiality issues under Section 308(d) Assurance of Confidentiality of the Public Health Service Act.³⁰

Key maternal health variables need to be standardized and aggregated at the national level to bring about necessary and effective efforts against maternal deaths and health disparities. Despite reported increases in maternal mortality rates and the potential for Maternal Mortality Review Committees to identify causes, a 2017 study published in *Obstetrics & Gynecology* identified that only 29 of the 50 states currently have such committees.³⁰ Still, there are certain state efforts that might be driving the change in how we assess maternal mortality and morbidity in light of racial disparities.

For example, in California, maternal mortality rates declined by 55 percent between 2006 and 2013, even as the national maternal mortality rates increased.³¹ Together, the California Department of Public Health and the California Maternal Quality Care Collaborative focused on three major components: research gathered from the California Pregnancy-Associated Mortality Review (CA-PAMR), the development of quality improvement toolkits based upon the CA-PAMR findings, and the creation of a maternal data center used by 90 percent of California's hospitals.³⁰

The Alliance for Innovation on Maternal Health (AIM) created several "bundles" of best practices for improving safety in maternity care.³² In 2013, the Safe Motherhood Initiative was launched in New York State by the American College of Obstetricians and Gynecologists (ACOG) District 2, supporting the implementation of similar best-practice "bundles" focused on obstetric hemorrhage, severe hypertension and thromboembolism.³² One hundred seventeen out of 124 hospitals in New York State are currently participating in this program.³²

In February 2019, ACOG District 2 issued a statement in support of meaningful legislation to establish a statewide maternal mortality review board and called for such legislation to ensure that the board's reviews are kept confidential to enable thoughtful and thorough reviews of the maternal deaths in New York State.³³ In that statement, ACOG District 2 stressed the confidentiality of the board's proceedings as critical to conducting meaningful maternal health quality improvement work and ultimately, achieving a reduction in preventable maternal deaths. Such legislation is currently pending in the New York State Senate.³⁴

The New York City Department of Health and Mental Hygiene (NYC DOHMH) has also developed a comprehensive, geographically coordinated structured system of care organized around a series of Regional

Perinatal Centers (RPCs), each supporting and providing clinical expertise, education and quality improvement to a group of affiliate hospitals. This system ensures that women and their babies have ready access to the services they need, including medical teams with experts in the management of complex maternal and fetal conditions. Maternal mortality review boards at the state level have begun a multidisciplinary review of each maternal death in New York State, aimed at identifying not only causes of death, but also other factors leading to maternal death, including its preventability and opportunities for intervention.

Understanding the impact of structural racism, implicit bias, and the sociocultural and historical contexts of social determinants of health on inequitable care has been addressed by New York State, NYC DOHMH and community-based organizations, such as Black Mamas Matter and the National Birth Equity Collaborative. According to Dr. Devine, "bias is the "implicit" aspect of prejudice... [the] unconscious activation of prejudice notions of race, gender, ethnicity, age and other stereotypes that influences our judgment and decision-making capacity."³⁵ Listening to the voices of mothers is an important step toward achieving reproductive and birth justice, and subsequently, birth equity. Birth equity has been defined by Dr. Joia Crear-Perry as "the assurance of the conditions of optimal births for all people with a willingness to address racial and social inequalities in a sustained effort."³⁵

Under the leadership of Governor Andrew Cuomo, New York State established Medicaid pilot projects to study the role of doulas in the birth experience. Implicit bias training programs for medical schools, academic medical centers, and health care providers at all levels have been proposed. New York State created the Taskforce on Maternal Mortality and Disparate Racial Outcomes, a multidisciplinary group of obstetrician-gynecologists, midwives, internists, community stakeholders, insurers, and professional organizations, such as ACOG District 2, Greater New York Hospital Association and the like, to identify a multi-pronged approach to review and better address maternal deaths with a focus on racial disparities, expanding community outreach and actions to increase prenatal and perinatal care. In 2010, New York State was 46th in the United States for lowest maternal mortality rate, and currently stands as 30th. The New York State Taskforce expanded the community health worker program, and plans to develop an Expert Workgroup on Postpartum Care in collaboration with NYC DOHMH and ACOG District 2 and create a data warehouse to house this information.³⁶

The NYC DOHMH has addressed respectful and accountable care by their New York City Birth Equity Initiative and the Sexual and Reproductive Justice Com-

munity Engagement Group Birth Equity Campaign. The latter three-year campaign from September 2017-2019 has engaged community members as “birth justice defenders,” who are provider champions to advocate for respectful care at birth. They have provided education and training to address the design and implementation of best practices within health care institutions, and have supported changes in institutional policies and practices that support these community-led initiatives.³⁷

The Society for Maternal-Fetal Medicine has published a special report on disparities in maternal morbidity and mortality, providing recommendations about immediate actions in clinical care, and describing existing research gaps. Health care system recommendations include supportive services and improved access to care with an emphasis on patient education, cultural competencies, telemedicine, and community-based initiatives. Clinical provider-specific recommendations include adherence to evidence-based clinical guidelines, the use of available preventive therapies, and early identification of women at higher risk for complications in pregnancy. Hospital-specific recommendations include the implementation of best-practice “bundles” to standardize care for common preventable complications, partnerships with low resource hospitals, implementation of multidisciplinary reviews of all cases of maternal death and severe morbidity, and a sharing of lessons learned from these reviews.³⁸ An analysis of a large national sample of community hospitals showed that most black women delivered in a concentrated set of hospitals, and these hospitals had a higher severe maternal morbidity rate. Preventive community-based programs and quality improvement efforts at these hospitals may result in improved outcomes.³⁹

Expanded insurance coverage for postpartum care, improved pre-conception and interconception care,⁴⁰ family planning and contraception to prevent unintended pregnancies,⁴⁰ including long-acting reversible contraception initiatives,⁴¹ the identification and optimization of chronic medical conditions, and the prolongation of breastfeeding as a strategy for chronic disease prevention are other critical steps. The New York State Perinatal Quality Collaborative was developed by the NYS Department of Health in order to ensure that evidence-based guidelines translate to clinical practice with the input of birthing hospitals, perinatal care providers, professional organizations, and other stakeholders.³⁸ Finally, funding for well-designed research studies is urgently needed to evaluate possible interventions, treatments, policies or actions that can reduce disparities.

V. Conclusion

Under social justice and human rights frameworks, all persons are entitled to have their basic human needs met, regardless of differences, such as economic disparity, class, gender identity, race, ethnicity, sexual orientation, citizenship, religion, age, disability or health status.⁴² We call upon the legal, social work, psychology, medical, nursing, midwifery and allied professional communities to join in robust advocacy for change in social policy aimed at decreasing maternal morbidity and mortality. This is nothing less than a moral imperative in this twenty-first century.

Endnotes

1. Institute of Medicine (U.S.) Committee on Understanding and Eliminating Racial and Ethnic Disparities in Health Care, Smedley BD, Stith AY, Nelson AR, editors, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care* (Washington, DC: National Academies Press 2003), <https://www.ncbi.nlm.nih.gov/books/NBK220358/>, doi: <https://doi.org/10.17226/12875>.
2. Giurgescu C, McFarlin BL, Lomax J, et al., *Racial Discrimination and the Black-White Gap in Adverse Birth Outcomes: A Review*, J. Midwifery & Women's Health (2011), 56(4):362-370, doi: <https://doi.org/10.1111/j.1542-2011.2011.00034.x>.
3. Rosenthal L, Lobel M, *Explaining Racial Disparities in Adverse Birth Outcomes: Unique Sources of Anxiety for Black American Women*, Soc. Sci. & Med. (2011), 72(6): 977-983, doi: <https://doi.org/10.1016/j.socscimed.2011.01.013>.
4. Grimm M, Cornish DL, *Infant Mortality and Racism in the United States*, Int'l J. Undergrad. Res. & Creative Activities (2018), 10:1-7, doi: <https://doi.org/10.7710/2168-0620.10977>.
5. Martin N, Montagne R, *Nothing Prevents Black Women From Dying in Pregnancy and Childbirth*, ProPublica (Dec. 7, 2017), available at <https://www.propublica.org/article/nothing-protects-black-women-from-dying-in-pregnancy-and-childbirth>.
6. Nuru-Jeter A, Dominguez TP, Hammond WP, et al., “It’s the Skin You’re in”: African-American Women Talk about Their Experiences of Racism. An Exploratory Study to Develop Measures of Racism for Birth Outcome Studies, *Matern. Child Health J.* (2009), 13:29-39, doi: <https://doi.org/10.1007/s10995-008-0357-x>.
7. Moller DW, *Strangers Among Us: Race, Poverty and End of Life*, In *Dying at the Margins: Reflections on Justice and Healing for Inner-City Poor*, (Moller DW, ed., New York, NY: Oxford University Press 2018), doi:10.1093/oso/9780199760145.001.0001.
8. Friedman JH, *Standard of care*, Commentary, R. I. Med. J. (2016), 99(6):8-9, <http://www.rimed.org/rimedicaljournal/2016/06/2016-06-08-friedman-rakatansky-korr.pdf>. Elliott JP, *The Medical and Legal Aspects of Maternal Mortality*, *Semin. Perinatol.* (2012), 36(1):73-78, doi: <https://doi.org/10.1053/j.semperi.2011.09.014>.
9. De Los Santos M, McFarlin CD, Martin L, *Interprofessional Education and Service Learning: A Model for the Future of Health Professions Education*, J. Interprof. Care (2014), 28(4), 374-375, doi: <https://doi.org/10.3109/13561820.2014.889102>. Bridges DR, Davidson RA, Odegard PS, et al., *Interprofessional Collaboration: Three Best Practice Models of Interprofessional Education*, J. Med. Educ. Online (2011), 16:1-10, doi: <https://doi.org/10.3402/meo.v16i0.6035>.

ANNA BURGANSKY, M.D., FACOG, is Assistant Professor of Obstetrics & Gynecology at Columbia University Medical Center (CUMC) and Director of Obstetrics & Gynecology at New York Presbyterian Lawrence Hospital. She is a board-certified obstetrician and gynecologist, practicing at Columbia Doctor's OBGYN office in Scarsdale, NY. She co-chairs the Quality Assurance Committee at CUMC and is an active member of ACOG's District II Safe Motherhood Initiative, where she's involved in development of guidelines and implementation of strategies aimed to reduce preventable obstetrical complications and maternal deaths in hospitals across New York State.

CAMILLE A. CLARE, M.D., MPH, CPE, FACOG, is Associate Professor of Obstetrics and Gynecology at New York Medical College. She is a board-certified obstetrician and gynecologist, and attending physician at New York City Health + Hospitals/Metropolitan in Manhattan, New York. She serves as the Director of Resident Research in her department. Presently, she is the Associate Dean of Diversity and Inclusion at New York Medical College. Dr. Clare has been an active member and leader on the section, district, regional and national levels of the American College of Obstetricians and Gynecologists (ACOG), currently serving as the ACOG District 2 Vice Chair, Vice Chair of ACOG Industrial Exhibits Committee and ACOG First Alternate on the Nominations Committee, District 2 Representative, and of the National Medical Association (NMA), currently serving as NMA Region 1 Trustee and Secretary-Treasurer of the Obstetrics and Gynecology Section of the NMA. Dr. Clare served on the Governor Andrew Cuomo Taskforce on Maternal Mortality and Disparate Racial Outcomes.

KAREN BULLOCK, Ph.D., LCSW, is a licensed clinical social worker and has practiced clinical social work in the states of New York, Massachusetts, Connecticut and North Carolina. She holds a research appointment at the Center for Health Intervention and Prevention, University of Connecticut, a Fellowship at the University of Michigan Program for Research on Black Americans, and is a Professor and Social Work Administrator at North Carolina State University. Dr. Bullock is a Board Member of the Social Work Hospice & Palliative Care Network, editor of the Innovative Practice Section of the *Journal of Social Work in Hospice & Palliative Care*, and currently serves as Chair of the National Association of Social Workers National Committee on Race and Ethnic Diversity, and Chair of the National Association of Social Workers Mental Health Practice Section.

MARY BREA MORRISSEY, M.D., is board certified by the American Board of Obstetrics and Gynecology. She earned a Bachelor of Science degree from the College of William and Mary. She was awarded her medical degree by the State University of New York Upstate Medical University. She completed her residency in obstetrics and gynecology at St. Luke's-Roosevelt Hospital Center where she served as chief resident. She joined WESTMED in August 2014.

IVELINA V. POPOVA, J.D., MBA, is a medical malpractice attorney at Garson & Jakub, LLP. She graduated from St. John's University School of Law in 2017. She has a health care administration background and is a member of the New York City Bar Association Bioethical Issues Committee and the American Health Lawyers Association.

MARY BETH QUARANTA MORRISSEY, Ph.D, MPH, J.D., is a health and social work researcher and New York health care attorney. She holds appointments at Fordham University's Global Healthcare Innovation Management Center and Graduate School of Social Service, and University of Rochester Medical Center's Finger Lakes Geriatric Education Center. Dr. Morrissey serves as President of the American Psychological Association Society for Theoretical and Philosophical Psychology; President of the Collaborative for Palliative Care; Chair of the Westchester County Bar Association Health Law Committee, and past Chair of the Women's Bar Association of the State of New York Health Law and Reproductive Rights Committee; member of the New York State Bar Association Health Law Section and Ethical Issues and Public Health Committees; and past president of the State Society on Aging of New York and the Public Health Association of New York City.

10. Betancourt JR, Green AR, Carrillo JE, et al., *Defining Cultural Competence: A Practical Framework for Addressing Racial/Ethnic Disparities in Health and Health Care*, Pub. Health Rep. 2003, 118:293-302, doi: 10.1016/S0033-3549(04)50253-4.
11. Cook K, Loomis C, *The Impact of Choice and Control on Women's Childbirth Experiences*, J. Perinatal Educ (2012), 21(3):158-68, doi: 10.1891/1058-1243.21.3.158.
12. Centers for Disease Control and Prevention, *Pregnancy Mortality Surveillance System, Trends in Pregnancy-Related Deaths*, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-mortality-surveillance-system.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2F%2Fmaternalinfanthealth%2Fpmss.html; Center for Disease Control and Prevention, *CDC Foundation Partnership to Help Reduce Maternal Mortality in the United States*, retrieved on January 5, 2019 at [https://www.cdcfoundation.org\(2016\)/pr/2016/cdc-foundation-partnership-help-reduce-maternal-mortality-united-states](https://www.cdcfoundation.org(2016)/pr/2016/cdc-foundation-partnership-help-reduce-maternal-mortality-united-states).
13. Payne R, *Racially Associated Disparities in Hospice and Palliative Care Access: Acknowledging the Facts While Addressing the Opportunities to Improve*, J. Palliat. Med. (2016), 19(2): 131-133, doi: <http://doi.org/10.1089/jpm.2015.0475>.
14. Bullock K, *The Influence of Culture on End-of-Life Decision Making*, J. Soc. Work End Life Palliat. Care (2011), 7(1):83-98, doi: <https://doi.org/10.1080/15524256.2011.548048>.
15. Dunkel Schetter C, Tanner L, *Anxiety, Depression and Stress in Pregnancy: Implications for Mothers, Children, Research, and Practice*, Current Opin. Psychiatry (2012), 25(2):141-148. doi: 10.1097/YCO.0b013e3283503680.

16. Lie DA, Lee-Rey E, Gomez A, Bereknys S, et al., *Does cultural competency training of health professionals improve patient outcomes? A systematic review and proposed algorithm for future research*, J. Gen. Intern. Med. (2011), 26:317-25, doi: <https://doi.org/10.1186/s12909-018-1450-5>.
17. Kilpatrick SK, Ecker JL, *Severe Maternal Morbidity: Screening and Review*, Am. J. Obstet. Gynecol. (2016), 215(3):B17-B22, doi: 10.1016/j.ajog.2016.07.050.
18. Callaghan WM, Creanga AA, Kuklina EV, *Severe Maternal Morbidity Among Delivery and Postpartum Hospitalizations In The United States*, Am. J. Obstet. Gynecol. (2012), 120(5):1029-1036.
19. Firoz T, Chou D, von Dadelszen P, et al. *Measuring Maternal Health: Focus on Maternal Morbidity*, Bull World Health Organ. (2013), 91(10):794-796, doi: 10.2471/BLT.13.117564.
20. Creanga AA, Bateman BT, Kuklina EV, et al., *Racial and Ethnic Disparities in Severe Maternal Morbidity: A Multistate Analysis, 2008-2010*, Am. J. Obstet. Gynecol. (2014), 210:435.e1-8, doi: <https://doi.org/10.1016/j.ajog.2013.11.039>.
21. Gyamfi-Bannerman C, Srinivas SK, Wright JD, et al., *Postpartum Hemorrhage Outcomes and Race*, Am. J. Obstet. Gynecol. (2018), 219:185.e1-10, doi: <https://doi.org/10.1016/j.ajog.2018.04.052>.
22. NYC DOHMH, *Severe Maternal Morbidity, 2008-2012*, <https://www1.nyc.gov/assets/doh/downloads/pdf/data/maternal-morbidity-report-08-12.pdf>.
23. Berg CJ, Harper MA, Atkinson SM, et al., *Preventability of Pregnancy-Related Deaths: Results of a State-Wide Review*, Am. J. Obstet. Gynecol. (2005), 106(6):1228-1234, doi:10.1097/01.AOG.0000187894.71913.e8.
24. NYS Department of Health, *Maternal Mortality Review, 2012-2013*, https://www.health.ny.gov/community/adults/women/docs/maternal_mortality_review_2012-2013.pdf.
25. Creanga AA, Syverson C, Seed K, Callaghan WM, *Pregnancy-Related Mortality in The United States, 2011-2013*, Am. J. Obstet. Gynecol. (2017), 130:366-373, doi: 10.1097/AOG.0000000000002114.
26. Moaddab A, Dildy GA, Brown HL, et al., *Health Care Disparity and Pregnancy-Related Mortality in the United States, 2005-2014*, Am. J. Obstet. Gynecol. (2018), 131(4):707-712, doi: 10.1097/AOG.0000000000002534.
27. *The States with the Highest and Lowest Maternal Mortality Mapped*, Advisory Board, November 9, 2018, <https://www.advisory.com/daily-briefing/2018/11/09/maternal-mortality>.
28. Tanner LD, Chen H, Chauhan SP, Sibai BM, *Racial and Ethnic Disparities in Maternal and Neonatal Morbidities Among College Educated Women*, Am. J. Obstet. Gynecol. (2018), 218(1): S558-S559, doi: <https://doi.org/10.1016/j.ajog.2017.11.430>.
29. Grobman W, *Racial and Ethnic Disparities in Adverse Obstetric Outcomes and in the Provision of Obstetric Care*, Am. J. Obstet. Gynecol. (2013), 208(1):S21, doi: <https://doi.org/10.1016/j.ajog.2012.10.206>.
30. Mayer R, Dingwall A, Simon-Thomas J, et al., *The United States Maternal Mortality Rate Will Continue to Increase Without Access to Data*, Health Affairs Blog (February 4, 2019), doi: 10.1377/hblog20190130.92512, <https://www.healthaffairs.org/doi/10.1377/hblog20190130.92512/full/>.
31. California Maternal Quality Care Collaborative, CA-PAMR (*Maternal Mortality Review*): *Maternal Mortality Rate – California and the United States; 1999-2013*, <https://www.cmqcc.org/research/ca-pamr-maternal-mortality-review>.
32. The American College of Obstetricians and Gynecologists, ACOG District II Safe Motherhood Initiative (SMI), <https://www.acog.org/About-ACOG/ACOG-Districts/District-II/Safe-Motherhood-Initiative?IsMobileSet=false>.
33. The American College of Obstetricians and Gynecologists Statement, *Enhancing New York's Maternal Mortality Review Process*, ACOG (February 11, 2019).
34. *An Act to Amend the Public Health Law, in Relation to Maternal Mortality Review Boards and the Maternal Mortality and Morbidity Advisory Council*, adding section § 2509, A.3276/S.1819, 2019-2000 N.Y. Leg. Sess. (2019), as this article goes to press this bill was enacted.
35. Crear-Perry J, *Systems and Policies Driving Black Maternal Health*, New York Academy of Medicine presentation, Maternal Mortality Summit, February 14, 2018, https://nyam.org/media/filer_public/92/4a/924a48f9-78bb-4bfe-8b4d-a6f87c88c062/joia_crear-perry_slides.pdf.
36. Governor Andrew Cuomo, *Social, Economic, and Racial Justice Agenda*, 2019 State of the State, <https://www.ny.gov/programs/2019-state-state-budget-address>.
37. Boyd LC, *New York City Maternal Morbidity and Mortality: Moving Data to Equitable and Sustainable Action*, New York Academy of Medicine presentation, Maternal Mortality Summit. February 14, 2018, https://nyam.org/media/filer_public/56/6b/566bc999-ad42-4215-b3e1-f1b62db447d7/lorraine_boyd_slides.pdf.
38. Jain JA, Temming LA, D'Alton ME, et al., *SMFM Special Report: Putting the "M" Back in MFM: Reducing Racial and Ethnic Disparities in Maternal Morbidity and Mortality: A Call to Action*, Am. J. Obstet. Gynecol. (2018), 218(2):B9-B17, doi: 10.1016/j.ajog.2017.11.591.
39. Howell EA, Egorova N, Balbierz A, et al., *Black-White Differences in Severe Maternal Morbidity and Site of Care*, Am. J. Obstet. Gynecol. (2016), 214(1):122.e1-127e7, doi: 10.1016/j.ajog.2015.08.019.
40. NYC DOH, Public Health and Health Planning Council, *Prevention of Maternal Mortality in New York State*, Public Health Committee Series and Recommendations for Action, January 2016, https://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/prevention_of_maternal_mortality.pdf.
41. Kacica M, *Reducing Maternal Morbidity and Mortality: Surveillance and Action*, New York Academy of Medicine presentation, Maternal Mortality Summit, February 14, 2018, https://nyam.org/media/filer_public/f4/57/f4571d2e-26e6-482f-8387-00f9268c963c/marilyn_kacica_slides.pdf.
42. National Association of Social Workers, Code of Ethics, Approved 1996, Revised 2017, <https://www.socialworkers.org/About/Ethics/Code-of-Ethics/Code-of-Ethics-English>.

Giving New Yorkers a Voice in Oversight of Hospital Consolidation

By Lois Uttley

Overview

Hospitals across New York State have been merging, closing and transforming at a rapid pace, changing the health care landscape that consumers must navigate. Forty-one acute care hospitals have closed across the state over the last 20 years, while others have eliminated emergency departments and maternity care. Nearly 500 acute care hospital beds were eliminated across the state in 2017. Large health systems have been steadily moving to acquire the remaining community hospitals, and now control 70 percent of the inpatient acute care beds in the state.

Hospital consolidation can require patients to travel to other locations to receive medical care from unfamiliar clinicians. Disabled and elderly patients, as well as those for whom English is not their primary language and those reliant on public transportation, may face particular challenges navigating changing delivery systems. While hospital executives often predict consolidation will improve care and efficiency, studies to date have not shown evidence of quality improvements. One recent study, in fact, warned that movement of care from one site to another through consolidation can pose threats to patient safety, if not carefully managed. Moreover, a number of recent studies have demonstrated that market consolidation can lead to increases in the price of health care, which are passed along to consumers through higher insurance premiums and deductibles.

Because of the significant consequences for patients, it is important that consumers have a say in state oversight of hospital consolidation. All too often, however, that does not happen, according to a study, “Empowering New York Consumers in an Era of Hospital Consolidation,” funded by the New York State Health Foundation and published in 2018 by the MergerWatch Project. Instead, consumers—taken by surprise when health systems announce planned closures or service reconfigurations—scramble to understand, influence or protest the proposals. The study concluded that New York’s 55-year-old Certificate of Need (CON) process should be updated to ensure that consumers are notified and engaged when their local hospitals propose to join health systems or plan to downsize, close or transform the way they deliver health services.

The study urged increased consumer representation on the state Public Health and Health Planning Council (PHHPC), which considers the most important hospital

transactions, and recommended steps to make the entire CON process more transparent and consumer-friendly. The study also suggested that New York follow the example of some neighboring states by including consideration of the potential impact of proposed hospital consolidation on the price of health care.

The Changing Health Care Landscape

Across the nation, the pace of hospital consolidation is accelerating and health care delivery is transforming. Some financially stressed community hospitals are downsizing, converting into urgent care centers or freestanding emergency departments, or closing. Especially hard hit are rural hospitals, more than 119 of which have closed since 2005.¹ Some urban hospitals, particularly those that are publicly owned and disproportionately serve uninsured and Medicaid patients, are also struggling. Nationally, 15 percent of hospitals are considered at risk of closure due to financial pressures.² Many of the remaining independent community hospitals are joining regional and national health systems. Between 2013 and 2017, nearly 1 in 5 of the nation’s 5,500-plus hospitals were acquired or merged with another hospital, according to Irving Levin Associates.³

There are many factors promoting consolidation, including clinical advances that make it possible to safely move treatment from inpatient hospitals to ambulatory sites. Another factor is payer demand for “value-based” care, necessitating capital investment in expensive technology to support collaboration among health care providers along the continuum of care, as well as administrative capacity to negotiate and manage value-based contracts. These requirements have proved challenging for smaller hospitals. Health systems have also acquired hospitals to increase market share, thereby gaining negotiating leverage with health insurers, as well as a larger patient base to feed the more specialized larger hospitals within each system. For rural and some urban hospitals, challenges may be precipitated by prohibitive costs to renovate ag-

LOIS UTTLEY, MPP, was founder and director of the MergerWatch Project. In 2018, she merged that project into the national consumer health advocacy organization, Community Catalyst, as part of a new Women’s Health Program, which she directs. She previously served as Director of Public Affairs for the New York State Department of Health and as Vice President of Family Planning Advocates of New York State. Co-authors of the study on which this article is based were Fred Hyde, MD, J.D., MBA; Patricia HasBrouck, MBA; and Emma Chessen, MPH.

ing hospital buildings, lack of access to capital and high percentages of patients who are uninsured or who are insured by (lower paying) Medicaid.

What has been happening in New York State? MergerWatch research found that a total of 41 hospitals have closed general inpatient services over the last 20 years. Sixteen of those hospital campuses have been converted to non-medical uses—such as condominiums, assisted living facilities, office space and schools—or are abandoned. The remaining 25 former hospital sites continue to be used for a range of medical services, such as clinics, labs, ambulatory surgery centers, urgent care centers, psychiatric treatment facilities, nursing homes and drug or alcohol rehabilitation centers. Some of these closings were recommended in 2006 by a state hospital “rightsizing” initiative called the Commission on Health Care Facilities in the 21st Century.

recent years. These systems now own or manage multiple hospitals, ambulatory surgery centers, urgent care centers and physician practices stretching over several counties. MergerWatch research found that the 12 largest systems in New York control more than half of the short-term acute care hospitals, 66 percent of inpatient beds, and account for more than two-thirds of all inpatient discharges.

Study Findings: New York’s CON Process Fails to Engage Affected Consumers

MergerWatch’s study of New York’s Certificate of Need (CON) process did not attempt to determine whether hospital consolidation is necessary or wise, but rather whether state oversight through CON is transparent to the public, engaging of affected consumers and appropriately protective of community access to timely, affordable care. The study compared New York’s CON policies and

“The trend of hospital consolidation, downsizing and transformation into outpatient facilities or freestanding emergency departments is likely to continue in New York.”

The number of hospital beds in New York has been steadily decreasing as facilities are downsized and transformed. New York State Department of Health data on hospital bed changes from 2015-2017 reveal a sharp jump in the number of beds lost, from 102 in 2015 up to 474 in 2017. The greatest reductions have been in the number of medical/surgical beds, which decreased by 402 beds over the three-year period. The next largest reduction was in psychiatric care (down 202 beds), followed by maternity care (down 88 beds) and pediatrics (down 80 beds).

The trend of hospital consolidation, downsizing and transformation into outpatient facilities or freestanding emergency departments is likely to continue in New York. More than 30 hospitals are financially endangered and would have closed or significantly reduced services within the past four years, absent extraordinary state support, according to recent presentations by New York State Department of Health (NYS DOH) staff.⁴

As individual New York hospitals change, merge and close, the health systems that began to take shape 20 years ago are growing in size, geographic reach and power, and strategically affiliating with or acquiring struggling community hospitals. Between January 2011 and September 2017, a total of 78 mergers or acquisitions were approved or pending, according to the Department of Health.⁵ Through such transactions, a small group of non-profit hospital systems have grown steadily larger in

procedures with those found in other states. Staff interviewed New York State Department of Health (DOH) staff and key organizational stakeholders of the CON process, such as hospital associations. The study included regular attendance at PHHPC meetings, including a PHHPC retreat held in September 2017, and review of a report the PHHPC issued in 2012 recommending CON reforms.

The MergerWatch study concluded that the current CON system in New York is not transparent to the public and fails to notify and engage consumers affected by hospital consolidation. Key findings were:

- **The consumer voice is not well represented on the 24-member PHHPC.** Public Health Law (Article 2, Section 220) specifies that “at least one member” of the PHHPC represent a consumer health advocacy organization. That “consumer seat” had been vacant from mid-2016 through early 2019, when this article was prepared. By contrast, New Jersey requires that five of the nine board members who review CON applications be consumer representatives. Maryland’s review board has 15 members, nine of whom are consumer representatives. Delaware’s board has four out of 15 members from the “public-at-large,” and requires that the Chair and Vice Chair of the board are both appointed from among those four members.

PUBLIC HEALTH LAW AND VULNERABLE POPULATIONS

- **Hospitals are being closed, downsized, merged into large health systems and/or transformed into outpatient care facilities without adequate public notice or engagement of affected consumers.** While state officials may encourage hospitals to hold community meetings, there is no state requirement for public hearings in the local community on proposed closure plans *in advance* of a planned hospital closing.
- **Hospital closings and most downsizing efforts (such as eliminating the emergency department or maternity services) are reviewed *only* by the NYS DOH staff and state Health Commissioner under “limited review” procedures.** These transactions are not subject to “full review” by the state’s Public Health and Health Planning Council (PHHPC) in public meetings at which consumers could be informed and provide comments.
- **Even when proposed transactions are subject to full review by the PHHPC, obstacles in the process frustrate potential consumer participation.** Meetings are not widely publicized and the agendas and voluminous exhibits are sent out electronically just one week in advance, to a list of people who must know to sign up to receive them. PHHPC meetings are held only in Albany or New York City, and only on weekdays. The lack of adequate advance notice that a particular transaction will appear on a PHHPC agenda makes it even less likely that affected consumers will be able to participate. It is difficult to find user-friendly information on the NYS DOH website about CON applications, the CON review process or how to submit written comments on pending applications. Copies of CON applications are not available on the website, leaving consumers in the dark about exactly what facilities are proposing to do. The NYSE-CON electronic system created by the NYS DOH is difficult for consumers to find and navigate.
- **The local CON review function once carried out by Health Systems Agencies (HSAs), all but one of which have closed due to funding cuts, has not been replaced with any organized system of soliciting and gathering consumer comments at the local level.** As a result, the place where an HSA recommendation would be included in DOH summaries of proposed transactions typically says “N/A.” A recommendation in a 2012 PHHPC report that Regional Health Planning Agencies be created and asked to provide local perspectives on CON applications was not implemented.
- **Unique to New York, hospital systems are allowed to begin the process of community hospital acquisition through “passive parent” relationships that are not subject to CON review.** These “passive parent” relationships are also not transparent to local health consumers—that is, their meaning for local health services availability and cost are unclear and often unexplored. CON review is required only when the parent system decides to apply for “active parent” status, often several years after the initiation of the “passive parent” relationship. By that time, acquisition of the community hospital has become viewed by hospital management (future employees of the merged system) as all but inevitable.
- **Although one of the original purposes of CON programs was to prevent unnecessary health cost increases, current CON review of hospital consolidations fails to consider whether these transactions might cause consumers, employers and insurers to pay higher prices.** This omission appears to be a missed opportunity at a time when studies are showing that hospital consolidation and resulting market concentration can lead to higher prices.⁶

Recommendations

The study produced recommendations for reform of the CON process, drawing on practices found in other states and, in some cases, recommendations from a 2012 PHHPC report that were not acted upon. Some of these recommendations could be fulfilled by changes in administrative practices and procedures. Others may require regulatory or legislative action.

1. Increase consumer representation on the PHHPC, and make the CON process more transparent and consumer friendly. The report urged the addition of more consumer representatives to the PHHPC to better ensure consumer views are heard. Following release of the report, nine major consumer health organizations and coalitions, including Health Care for All NY, Medicaid Matters and Consumers Union, wrote to Governor Andrew Cuomo urging appointment of consumer health advocates to fill the long-vacant consumer seat on the PHHPC, as well as another vacant seat. A similar letter was sent by a group of New York City Council members and state legislators. Two of those lawmakers, Assembly Health Committee Chair Richard Gottfried and State Sen. Brad Holyman (who both represent Manhattan districts in which St. Vincent’s Hospital closed precipitously and Beth Israel Medical Center has announced a dramatic downsizing) have introduced legislation (A.4071 and S.00870) in 2019 to increase the number of PHHPC members to 34 and

require that at least four be consumer health advocates. That legislation has been approved by both the Assembly and Senate, and will go to the Governor.

Other study recommendations in this category included making it easier for consumers to find hospital CON applications on the NYSDOH website and to submit comments on them. One suggestion was requiring CON applicants to submit Letters of Intent 30 days prior to the filing of a CON, and posting those Letters of Intent promptly on the NYSDOH website, following a model found in the state of Washington.

2. Ensure that consumers who would be affected by proposed hospital closures or elimination of key hospital services are notified well in advance, and engaged in reviewing proposed closure plans. The study recommended requiring 90 days advance notice and provision of a proposed closure plan, as well as a public hearing in the affected community at least 60 days in advance and a full review of these transactions in public meetings by the PHHPC.

Multiple states require advance public notice when a hospital intends to close completely or discontinue essential services. Currently, New York State does not. Instead, New York requires a public hearing to be held by the Department of Health *within 30 days after* hospital closure and the DOH is expected to post information from that hearing within 60 days after that.⁷ Moving the public notice to a period *before closure* and putting the responsibility on the hospital to help inform the public would greatly increase transparency and allow members of the affected communities to better prepare for impending changes.

Notice requirements are already in place in New York State for other non-health oversight processes. For example, under the New York Worker Adjustment and Retraining Notification (WARN) Act, employers with more than 50 full-time employees must give 90 days' warning prior to any significant changes in employment. This notification must be given to the affected employees, Department of Labor, employee representatives, and the Local Workforce Investment Board. Since hospitals are large employers, they must already be required to notify their employees well in advance of closures and downsizings. The required practices from the WARN Act could be extended to residents of the communities that would be affected by hospital downsizings or closings, as well as public officials from those communities. The study recommended hospitals should be required to post notices at their facilities, and send a press release to all local newspapers and broadcast/on-line media, and to relevant local officials. The Department of Health should also post these announcements on its website.

When hospitals or systems give this notice, they should be required to provide a rationale for closure or elimination of services, including, but not limited to the following information: last year's service volume for the hospital or for the services to be eliminated; projected community need for the service within the hospital's service area; and details about where patients will be able to obtain access to the affected care once it is no longer at that facility. The CON applicant seeking approval to reduce, eliminate or relocate a service should be required to describe the "effect on the ability of low-income persons, racial and ethnic minorities, handicapped persons and other underserved groups and the elderly to obtain needed health care."⁸

This closure plan should be submitted to the DOH and disseminated to the general public through local officials, provision to local media and through posting on the NYS DOH website. Provision of this plan would give consumers the opportunity to provide informed comments at the public hearing we urge be required prior to such closure, and would enable NYS DOH officials to work with local health officials to ensure continued access to care, including by requiring modifications to the closure plan and/or assessing the ability of remaining providers to fill the resulting service gap. This process would also give consumers time to understand any changes to their care and ensure they are still able to access the same services in a reasonable way.

The study also urged that the state require at least one public hearing in the affected community, at night or on a weekend, at least 60 days in advance, when a hospital proposes to close, downsize or close a key service, such as the emergency department or maternity services. Public hearings are a vital way to engage members of the community, provide them with information on how their local hospitals are proposing to change and elicit consumer comments that could affect closure plans. Vermont, New Jersey and North Carolina are three states that provide potential models of how to use public hearings to engage affected consumers. In Vermont, the Green Mountain Care Board, which evaluates CON applications, holds a public hearing for every application, with few exceptions for expedited review. Members of the public can also submit written comment on an application up to 10 days after the public hearing.

New Jersey holds public hearings when there is an application for a change in ownership or to close a health facility. North Carolina goes an important step further. Although they do not mandate a public hearing on every application, they require one for projects that are seen as competitive, that spend more than \$5,000,000 on construction or downsizing/closing or relocation of services, that are determined to be in the public interest by the State

Health Planning and Development Agency or for which an “affected party” requests a hearing. In North Carolina, an “affected party” is defined broadly. This can be any person living in the area served by the applicant, anyone who uses health facilities in that area, any provider who practices in the area, a third party payer for facilities in the area, and includes the applicant. Most significantly, North Carolina holds hearings in the service area that is impacted. The department works with the members of the community to hold the hearing and make it accessible, so that the public may express concerns or comments on their local facility. A system like this could greatly improve consumer engagement around New York State.

The study urged adoption of a requirement for a public hearing in the affected community at least 60 days in advance of a proposed hospital closing, downsizing or closing of a key time-sensitive service, such as the emergency department or maternity services. The authors acknowledged that NYS DOH staff members do not have the capacity to organize, publicize or run multiple public hearings around the state each year. Instead, the study suggested that local Population Health Improvement Program (PHIP) entities or county health departments be asked to take on the responsibility of organizing and publicizing public hearings for facilities in the areas they oversee, in collaboration with the hospital seeking CON permission to close or downsize.

3. Require “full review” CON applications, with opportunity for public comment, for closing of a hospital or for elimination of any hospital unit or service that could compromise timely and affordable access to those services in the affected community, as well as for converting emergency departments to part-time operation. Full review should also be required for “transformation” of multiple units within a hospital to ambulatory settings.

The study urged that “full” CON review by the PHHPC in public meetings be required for hospital closings, elimination of units that provide time-sensitive care, such as emergency departments or maternity services, and for hospital downsizing or transfer of services and/or beds from one facility to another within a given health system, when such transfers could have a potential negative affect on the availability of timely, affordable care in the affected community.

Given the trends described earlier in this article—particularly the movement of services from hospital inpatient settings to outpatient settings—it is particularly important to improve the transparency of hospital “transformation” initiatives and more fully engage affected consumers in reshaping local health delivery systems.

Currently, hospitals and health systems are being allowed to file a series of multiple, narrowly framed

“limited review” CON applications to decertify beds and services over time. Through this process, hospital systems are able to gradually close facilities unit by unit and move services either to their other hospitals or to ambulatory settings without undergoing full CON review at a public meeting. An example of this use of limited review CONs involves Mount Sinai Beth Israel in Manhattan. From November 2016 to March 2017, Mount Sinai submitted a series of limited review applications to close or decertify beds in multiple units, including maternity care, cardiac surgery and pediatric intensive care. Full CON review by the PHHPC (with opportunity for public comment) will be required only when the system proposes to build a new facility (such as the 70-bed hospital Mount Sinai plans to construct to replace its current much larger facility).

The study recommended that if a hospital (or its parent health system) seeks to close (or transfer elsewhere, such as to an ambulatory setting or a different facility within the system) more than one service within a year, it should be mandated to go through full CON review to do so. Within this full CON review, hospital systems should be required to lay out their plans for how and where health consumers will obtain those services in the future, how patients will be kept informed and what they should expect their new system to look like in the next three to five years. A transformation plan should explain the likely impact of the proposed delivery system changes on consumers who rely on Medicaid or are uninsured, and those for whom travel to other facilities may present an obstacle to obtaining care. This information is necessary for community members to understand how and where they will be accessing the care they need, potentially at new locations, and to provide comments to the PHHPC and DOH to inform CON decision-making.

4. Improve transparency, consumer engagement and post-transaction accountability when hospitals join health systems.

While there can be positive results when community hospitals join large health systems, there can also be downsides, such as loss of local control of a community hospital. Executives of these large systems can and do make decisions to close services at local hospitals (such as emergency departments and maternity care) and direct consumers to other facilities within the system that offer the care. The result could be reduced access to care within a community and longer travel times to obtain care. Health system consolidation and the movement of care into new sites can also pose risks to patient safety if not carefully managed, warned Dr. Atul Gawande and colleagues at the Harvard School of Public Health and Brigham and Women’s Hospital in a recent JAMA article.⁹ In such situations, the authors point out, clinicians frequently must travel to new practice settings, navigate

unfamiliar infrastructure and care processes, and treat different types of patients. Consolidating a system's service line—such as obstetrics, psychiatry or substance use treatment—at one facility could increase the number of patients being seen at that facility and introduce types of patients with whom the clinicians are not familiar, creating cultural and other barriers to good quality care. The authors have developed a patient safety toolkit to guide management of system changes and expansion of practice sites.

When system takeovers of local hospitals are proposed, the affected consumers deserve to know the full implications, both positive and negative. One of the obstacles to such transparency is the use in New York State of “passive parent” governance by systems to begin takeover of community hospitals without any CON review. No other state allows for the distinction between passive and active parent in system takeovers of local hospitals. The level of transparency and accountability in the arrangement is simply too low. The study urged that New York eliminate “passive parent” governance and allow only an “active parent” relationship that requires full CON approval, so that all of the issues associated with such consolidation can be grappled with in public and with focus. In addition, we recommend that mergers, acquisitions, and “active parent” relationships be made subject to post-transaction monitoring to allow for increased oversight of changes to large health systems.

For transactions involving a consolidation, the study recommended requiring CON applicants to clearly articulate the public need served by the transaction and provide long-range plans (at least three years) predicting the impact on affected patients' ability to obtain care. The study further recommended requiring a public hearing in the affected community to solicit consumer comment and a plan for continuing engagement of local health consumers in governance of the hospital.

Recognizing the significant changes that can occur with changes of governance, Connecticut requires the provision of a three-year plan for all transactions that involve a change of ownership. This plan must include a description of how health care services will be provided in the first three years after the change in ownership, including any planned introduction of new services or elimination, consolidation or reduction of existing services.¹⁰

The study recommended a similar requirement in New York, with some additional features. For all transactions involving consolidation of hospitals, the CON applicant should be required to articulate how the transaction will serve a public need, such as providing services not currently available in the hospital's catchment area, strengthening the quality of care or addressing public

health priorities that have been identified by local health departments or health planning partnerships. Even if the transaction is seeking to simply provide better access to capital for the smaller hospital, addressing the issue of public need should help to make the reasons for the active parent status more transparent. The application should also explain how local participation in governance of the hospital will be maintained following the acquisition, merger or establishment of active parent powers, such as through maintaining seats on the hospital board for local representatives.

The applicant should also be asked to describe how the new governance arrangement would affect the current service delivery patterns, such as relocating some services to other facilities, closing units of the hospital or establishing referrals to a system's center of excellence for certain types of complex care. For each planned reconfiguration of services, the applicant should be required to explain how patients would be assisted in traveling to new locations and navigating an unfamiliar system of care. As well, the applicant should predict how current case mix (provision of Medicaid clients vs. commercially insured clients, those with Medicare and those with no insurance) would potentially change under the new arrangement.

The study concluded that post transaction monitoring and oversight is necessary for hospital mergers and when health systems become active parents of community hospitals. For such transactions, the study recommended requiring the CON holder to provide yearly reports to the DOH and PHHPC for a period of three to five years. These reports should describe any changes in service configurations or case mix that have occurred since project approval and demonstrate adherence to any conditions that were attached to the CON approval. In addition to the reports provided by the applicant, an “independent monitor” could be hired to act as a compliance reporter for large mergers and acquisitions. Such reporting would increase transparency of the actual effects of the transaction and could lead to an extension of a limited life CON, with increased pressure to comply with terms of the approval in order to win a permanent CON.

Connecticut has a system of “post-transfer independent consultants” in place to monitor the progress of larger mergers, meet with representatives from the parent organization and its new affiliate, and report back to the state's Office of Health Care Access. The “monitor,” often a consulting or public accounting firm, is selected by the applicant and approved by the state agency. The applicant pays for the monitor, and reports to the state on matters involving compliance of the applicant with “conditions” established in the awarding of the CON. This process allows for more oversight and accountability of new active parent relationships. In addition, more active monitoring

would assist the DOH in gathering information about trends in mergers and acquisitions to better understand the current system as a whole.

5. Require CON review of major proposed transactions, such as hospital mergers and system acquisition of hospitals (but not hospital closings), to include consideration of the potential impact on the price of health care.

While one of the original purposes of state Certificate of Need programs was to control costs at a time of hospital expansion, construction and equipment acquisitions, there is little evidence in the literature that this goal has been fulfilled. As trends have shifted from hospital expansion to consolidation, there is a new opportunity to employ CON to restrain price increases that are associated with health systems acquiring greater market share through consolidation, takeovers of community hospitals, and acquisition of outpatient centers and physician practices.

Consolidation in the health industry (both hospital mergers and hospital acquisitions of physician practices) is widely recognized as leading to greater market power for large health systems and thus higher prices charged to insurers. For example, a Robert Wood Johnson survey¹¹ of studies reported that, when hospitals merge in already concentrated markets, price increases might exceed 20 percent. More recently, Cooper, Gaynor and others¹² found that the primary determinant of health care costs is the price of provider services, and that the most powerful determinant of provider price is market power—not quality, not size, not academic status or reputation. A 2018 study conducted for the *New York Times* by researchers from the Nicholas C. Petrakis Center at the University of California, Berkeley, examined 25 metropolitan areas with the highest rate of consolidation from 2010 through 2013 (including the Albany, NY, market.) The study found that the price of an average hospital stay soared, with prices in most areas going up between 11 percent and 54 percent in the years afterward.¹³

A 2016 study for the New York State Health Foundation by Gorman Actuarial found that “a hospital’s market leverage—its bargaining power when negotiating with insurers—is a key factor in the prices a hospital can command.”¹⁴ The study reported that hospitals with greater market share are generally higher priced, and those higher prices extend to hospitals that are part of a hospital system with large regional market share, regardless of an individual hospital’s size or market share. A study by the Massachusetts Health Policy Commission¹⁵ found that market power is the primary determinant of hospital prices in that state. The Attorney General of Massachusetts made similar findings¹⁶ in 2010. Another

contributor to price increases is that community hospitals are generally paid less for their services by third parties than are “academic” health systems that are acquiring the smaller hospitals.

The NYS DOH and PHHPC reviews of CON transactions do not explicitly examine the potential impact on the price of health care in a region. Instead, the financial aspects of CON review are focused on the financial feasibility of the project—essentially whether the applicant can afford to carry it out, and what the long-term impact of the project would be on the applicant’s financial health.

The study recommended consideration of the potential impact on the price of care in DOH and PHHPC review of selected “full review” CON applications (such as system takeovers of formerly independent hospitals or mergers of nearby facilities). DOH staff time currently spent on analyzing the “financial feasibility” of a project, a procedure DOH staff describe as time consuming and most often of “low value,” could be redirected to assessing the potential impact on health care prices.

One possible method of doing this would be to ask CON applicants to predict the effect of their proposed transactions on their prices. Another method would be to require an outside assessment, such as by a consultant. Another approach would be to use data reporting submissions from health plans, as the New York State Department of Financial Services did through a mandated Request for Information it issued to inform a 2016 report on hospital pricing in New York.¹⁷ As the state moves to implement an All Payer Database,¹⁸ this could be a valuable resource for assessment of the actual price effects of hospital mergers.

When it comes to analyzing and monitoring project price increases associated with a CON application, third parties may be useful. Staff of the Attorney General’s Anti-Trust Bureau, for example, have expertise in assessing the likely effect on price of anti-competitive business transactions. Insurers are also able to analyze predicted price increases associated with hospital consolidation and track the actual price increases.

Endnotes

1. Data from North Carolina Rural Health Research Program, cited in Mincer, J., *More hospital closings in rural America add risk for pregnant women*, Reuters, July 18, 2017, accessed at <https://www.reuters.com/article/us-usa-healthcare-rural/more-hospital-closings-in-rural-america-add-risk-for-pregnant-women-idUSKBN1A30C5>.
2. Ellison, Ayla. *450 Hospitals at Risk of Closure*, Morgan Stanley Analysis Finds, Becker Hospital Review, 20 Aug. 2018. <https://www.beckershospitalreview.com/finance/450-hospitals-at-risk-of-potential-closure-morgan-stanley-analysis-finds.html>.
3. Kaiser Health News. *When Hospitals Merge*, US World News Report, July 23, 2018, <https://www.usnews.com/news/healthiest->

PUBLIC HEALTH LAW AND VULNERABLE POPULATIONS

- communities/articles/2018-07-23/what-happens-when-a-community-hospital-is-sold-to-a-large-corporation.
4. NYS DOH presentation, "Priority Next Steps for Transformation of Health Care Delivery System: Beyond the Walls of 'H'." Rethinking CON and the Regulatory Framework," given at the Public Health and Health Planning Council Strategic Retreat, Tarrytown, NY, Sept. 7, 2017.
 5. *Id.*
 6. Weil, A., *Market Concentration* and accompanying article by Fulton, B., *Health Care Market Concentration Trends in the United States: Evidence and Policy Responses*, in *Health Affairs*, Sept. 2017 issue.
 7. NYS Public Health Law- Article 28, section 2801.G, accessed at <http://codes.findlaw.com/ny/public-health-law/pbh-sect-2801-g.html>.
 8. Section 709.1, pursuant to section 2802 of the Public Health Law.
 9. Haas, S., Gawande, A., Reynolds, M., *The Risks to Patient Safety From Health Systems Expansions*, *JAMA*, April, 6, 2018.
 10. Connecticut Office of Health Care Access, Certificate of Need (CON) Process Statutory Authority, Section 19a-639.12d.2B.
 11. Gaynor, M. and R. Town, *The impact of hospital consolidation – Update*, Robert Wood Johnson Foundation, Synthesis Report, June 2012.
 12. Cooper, Z. et al, *The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured*, NBER Health Care Pricing Project, December 2015.
 13. Abelson, R., *When Hospitals Merge to Save Money, Patients Often Pay More*, *New York Times*, Nov. 14, 2018, <https://www.nytimes.com/2018/11/14/health/hospital-mergers-health-care-spending.html>.
 14. New York State Health Foundation, *Why Are Hospital Prices Different? An Examination of New York Hospital Reimbursement*, prepared by Gorman Actuarial, Dec. 18, 2016.
 15. Massachusetts Special Commission on Provider Price Variation Report, March 15, 2017.
 16. Office of Massachusetts Attorney General Martha Coakley, *Examination of Health Cost Trends and Drivers*, Report for Annual Public Hearing, March 16, 2010.
 17. New York State Health Foundation, *Why Are Hospital Prices Different? An Examination of New York Hospital Reimbursement*, prepared by Gorman Actuarial, Dec. 18, 2016, <https://nyshealthfoundation.org/resource/an-examination-of-new-york-hospital-reimbursement/>.
 18. The purpose, design and timeline for New York's implementation of an All Payer Database are described here: https://www.health.ny.gov/technology/all_payer_database/.



Lawyer Assistance Program

Your **First Choice**
or Your **Last Resort**

Call us when you see the early warning signs...
missed deadlines, neglected email, not returning phone
calls, drinking too much, feeling sad and hopeless.

OR

Call us when you see the consequences of ignoring
the early warning signs... work problems, relationship
difficulties, an arrest, fired from your job, notice from
grievance.

Call **1.800.255.0569**

NEW YORK STATE BAR ASSOCIATION
LAWYER ASSISTANCE PROGRAM

www.nysba.org/lap



Housing Rx: Policy Innovations and Opportunities for Action in New York State

By Madeline Morcelle and Leila Barraza

Introduction

Homelessness and poor health are deeply intertwined. People with complex and difficult-to-manage chronic and behavioral health conditions are at disproportionate risk of losing stable housing and experiencing homelessness.¹ In turn, people experiencing homelessness face tremendous access and cost barriers to essential preventive, treatment, and related supportive services and medication adherence, resulting in disproportionate rates of morbidity and mortality from acute, chronic, and behavioral health conditions. As a result, they are three times more likely than the general population to visit an emergency room each year.² Individuals experiencing chronic homelessness, living with a severe mental illness, or both have average direct health care costs ranging from \$10,000 to \$60,000.³ Decades of studies document how investment in solutions to homelessness such as Housing First, a model that provides permanent supportive housing without preconditions and barriers to entry (e.g., sobriety or treatment participation requirements) can dramatically reduce downstream health care costs.

Today, no state in the U.S. has an adequate supply of affordable rental housing for the lowest income renters.⁴ The issue is extensive in New York State, where only 35 rental homes are affordable and available per 100 extremely low-income renter households, and 71 percent of these households are extremely cost-burdened, spending more than half of their income on housing costs and utilities. Under these conditions, many individuals and families struggle to keep up with or spend a majority of limited income on rent and utility costs, live in overcrowded conditions, and are forced to move frequently. Many are just one hospital bill, layoff, or other emergency away from eviction and homelessness. In 2017, homelessness increased for the first time nationwide in seven years, and on a single night in January of that year, 16 percent (89,503) of all people experiencing homelessness in the U.S. resided in New York.⁵ From 2007–17, New York saw a 43 percent increase in homelessness—the biggest jump across the country.

These housing and health inequities will continue absent both targeted interventions to assist individuals in crisis and action to address their root causes across sectors, including unjust distributions of power and other health-related community resources. Recent federal housing proposals and policies inadequately and sometimes antagonistically address these issues. For

example, due to insufficient funding levels, only one in four low-income families who qualify for federal rental assistance currently receive it, and many remain on waiting lists for years, often resulting in eviction and homelessness.⁶ In spite of existing shortfalls, in early 2018, the Trump administration sought to gut federal funding for housing assistance. Some state and local policymakers have sought to increase affordable housing stock by establishing bonds for affordable housing and requiring cities to permit midsize apartment construction around train stations and certain bus stops, among other housing policy interventions.⁷ Meanwhile, some of the most innovative and promising legal and policy responses to growing housing instability and homelessness seek to bridge the traditionally disparate worlds of housing and health. Cutting-edge Medicaid payment and service delivery reforms and public health policies challenge those siloes through both targeted individual and population-level interventions such as housing as health care and Medical-Legal Partnership. Even in an uncertain federal health policy environment, state policymakers and health care payers can build on these foundations, leveraging emerging legal infrastructure and novel reforms to treat and prevent homelessness.

Housing as a Prescription for Health

Signature federal policy responses to the HIV/AIDS epidemic recognize the critical importance of housing as health care for people living with HIV, who face heightened barriers to housing stability and dramatically lower percentages of viral suppression if experiencing homelessness. Through the Cranston-Gonzalez National Affordable Housing Act of 1990, Congress established Housing Opportunities for Persons with AIDS (HOPWA), creating dedicated housing and related supportive services to meet the needs of people living with HIV. For years, the federal Ryan White HIV/AIDS Program (Ryan White) has financed key services addressing recipients' social determinants of health, including housing, legal, transportation, and nutrition services.

MADeline MORCELLE, J.D., M.P.H., is a Staff Attorney at the Mississippi Center for Justice. **LEILA BARRAZA**, J.D., M.P.H., is an Assistant Professor at Mel and Enid Zuckerman College of Public Health, University of Arizona.

Yet federal Medicaid policy has lagged behind Ryan White and HOPWA in addressing housing to improve health. For years, Congress and the Centers for Medicare and Medicaid Services (CMS) neglected the potential for Medicaid to help address beneficiaries' housing needs. The Patient Protection and Affordable Care Act of 2010 (ACA) established a novel set of state plan authorities designed to enhance access to care coordination and community-based services, spurring interest in potential opportunities to integrate housing and health. Although Congress specifically barred federal financial participation for room and board in home and community-based settings,⁸ opportunities to enhance housing stability and address homelessness emerged. In 2015, CMS' Center for Medicaid and CHIP Services published a bulletin recognizing the case for housing-related activities and services in Medicaid and clarifying authorities for states to cover housing-related activities and services in new Medicaid benefits.⁹ In 2016, CMS' Innovation Center created the Accountable Health Communities Model to test how addressing Medicaid and Medicare beneficiaries' health-related social needs, such as housing, through screening, referral, and community navigation services would influence health care costs and reduce utilization.¹⁰

In the midst of this evolving federal policy landscape, states increasingly sought state plan waivers and amendments to integrate allowable housing supportive services into new health care delivery models.¹¹ Some, such as New York, went further, braiding state dollars into program funding streams to cover otherwise unallowable room and board and utility costs. In January 2011, Governor Andrew Cuomo launched a new Medicaid Redesign effort to address health care costs and improve care, with a focus on meeting the significant health needs of the 20 percent of beneficiaries whose care generates 75 percent of all Medicaid spending.¹² A Medicaid Redesign Team (MRT) Affordable Housing Workgroup evaluated barriers to the efficient use of existing housing resources and identified solutions. Based on its final recommendations, the state created a new MRT Supportive Housing program to provide service funding, rental subsidies, and capital dollars to create and finance supportive housing and long-term care programs for beneficiaries and authorized \$75 million for housing services for FY 2012–13. Over time, the state's investments in housing have grown and become an integral part of MRT implementation, increasing in importance in 2014 when New York expanded Medicaid and nearly all residents experiencing homelessness became eligible. That same year, CMS approved New York's Section 1115 waiver application, which aimed to reinvest \$8 billion in cost savings from Medicaid Redesign Team (MRT) reforms back into the state's health care system.¹³

From 2012–17, MRT's supportive housing programs—including rental subsidies, capital construction, and pilot projects testing innovative models of integrated care—served over 12,000 vulnerable high-cost Medicaid beneficiaries.¹⁴ New York's MRT Supportive Housing program reaffirms the efficacy of housing as health care through a 40 percent decrease in hospital inpatient days, 26 percent decrease in emergency room visits, and 44 percent decrease in patients with substance abuse rehabilitation admissions. Not only has the project improved the health of beneficiaries, but the savings to Medicaid are notable as well, with a 15 percent overall reduction in Medicaid health expenditures. NY could further establish housing services within the health care continuum by empowering providers to prescribe housing as a treatment for homelessness. For example, a bill introduced in the Hawaii legislature in 2017 would have allowed re-classification of homelessness as a medical condition, redefining health care delivery by permitting health care providers to prescribe housing as treatment for those in need.¹⁵ The plan for payment included funding used by Medicaid to pay for such housing prescriptions designed to prevent costly and frequent emergency room visits by people experiencing homelessness.

Promoting Housing Stability Through Medical-Legal Partnership

Strategic multilevel action through Medical-Legal Partnership (MLP) can usher in a new standard of care for people at risk of or experiencing homelessness, resolving individual and systemic health injustices through individual legal services and policy advocacy. MLP is a health care delivery model that integrates legal service attorneys into clinical health care teams. As of December 2018, more than 300 MLPs nationwide provide individual legal assistance to resolve serious health-related social needs that, if untreated, often result in or perpetuate chronic cycles of homelessness, such as housing and employment discrimination, landlord and tenant issues, eviction, and barriers to public benefits.¹⁶ Emerging research demonstrates how MLP can successfully address the housing needs of people experiencing homelessness. For example, a study examining the impact of MLP services on veterans experiencing chronic homelessness, living with serious mental illness, or both in New York and Connecticut found improvements in housing status. Where individual representation is insufficient to address legal barriers, some MLPs advocate for policies to address the systemic drivers of homelessness and other social challenges. For example, MLP attorneys and health care providers have leveraged their combined medical and legal knowledge and learnings in strategic policy advocacy, securing regulatory changes to prevent utility shutoffs and extend personal safety protections.

MLPs are uniquely positioned to advocate for life- and cost-saving solutions to homelessness, but in order to scale and sustain the model and maximize potential population health improvements through multilevel advocacy, more available, sustainable, and flexible funding sources are needed. Reliable and renewable funding sources for MLPs are still chronically limited, and MLP partners funded through the Legal Services Corporation are subject to prohibitions on lobbying and activities attempting to influence legislative activities.

To address these gaps, in 2007, the New York Legal Assistance Group's (NYLAG) LegalHealth division launched an advocacy campaign to secure state funding to scale the MLP model statewide.¹⁷ Despite initial legislative and gubernatorial support, its \$2 million budget proposal to establish 15 new MLPs across the state as well as one oversight entity to provide technical assistance became a casualty of the 2008 economic crisis. As the crisis deepened, NYLAG, coalition partners, and legislative champions decided to focus on unfunded policy alternatives. In 2011, New York became the first state to endorse the importance of integrating free legal services into health care settings by creating a certification process for "health-related legal services programs." Under the amended New York State Public Health Law § 22, legal entities may register with the Department of Health as "Health-Related Legal Services Programs," better positioning them to secure funding sources as the economy improved. In 2014, Georgia became the second state to establish a certification process for MLPs—this time, for the purpose of determining eligibility for grants.¹⁸

Federal, state, and private health care policymakers have an opportunity to fortify MLPs—including state-certified programs—through parallel Medicaid payment reforms integrating financing for MLP services in both traditional and managed care settings. For example, California's renewed Section 1115(a) demonstration waiver (effective 2015–20) authorizes Whole Person Care (WPC) county-based pilots that provide service integration and other strategies to improve health outcomes and reduce costs for vulnerable and high-utilizing Medicaid recipients.¹⁹ In addition to providing a specific option for WPC Pilots to focus on providing housing and supportive services for individuals at risk of or experiencing homelessness with a demonstrated medical need for housing or supportive services, the waiver enables WPC Pilots to focus on a broad range of patient-centered strategies coordinating physical health, behavioral health, and social services. In September 2017, the Los Angeles County Department of Health Services published a Request for Applications for organizations to provide MLP services under its WPC Pilot (WPC-LA).²⁰ The following spring, WPC-LA launched its county-wide Medical-Legal Community Partnership (MLCP) network. Leveraging

Medicaid and other funding sources, the MLCP aims to provide an estimated 2,500 technical assistance/advice calls, 1,000 brief service interventions, 100 administrative appeals, and 50 litigation cases.

Innovative payment reforms can also increase access to MLP services in a managed care context. In August 2018, North Carolina published its new Request for Proposals for Medicaid Managed Care Prepaid Health Plans, requiring that they "provide access to medical-legal partnerships for legal issues adversely affecting health, subject to availability and capacity of medical-legal assistance providers."²¹ While the provision does not require Prepaid Health Plans to fill service gaps by establishing new MLPs, it could spell new funding sources for sustaining and scaling existing MLPs—key homelessness prevention and treatment service providers—within North Carolina's rapidly evolving managed care landscape.

Conclusion

In spite of federal attempts to undermine and repeal the ACA and limit Medicaid eligibility through punitive reforms, recent CMS actions signal fertile if mercurial ground for continued innovation at the interface of housing and health. In October 2018, CMS approved Hawaii's Section 1115 waiver application seeking federal reimbursement for community integration (e.g., supportive housing) services for beneficiaries experiencing or at risk of homelessness who also have a disability, mental health condition, substance use disorder, or complex health needs.²² The following month, U.S. Secretary of Health and Human Services Alex Azar signaled political will for "bold" whole-person solutions that address beneficiaries' social determinants of health beyond screening and referrals with value-based payment reforms to match, foreshadowing increased flexibility for states, managed care organizations, and health care organizations to address beneficiaries' housing needs, including capital costs.²³

In this uncertain yet auspicious moment, state policymakers and health care payers cannot afford to forego innovation. Insufficient affordable housing stock, evictions, and homelessness have created a severely unjust and costly national public health crisis. Novel Medicaid and public health policy reforms that traverse traditional boundaries between health care, housing, and related enabling services provide a strong foundation for reversing and ending the root causes of resulting population health inequities. Public and private policymakers can improve societal outcomes by scaling and fortifying legal and policy efforts that connect the traditionally siloed worlds of housing and health for individuals and communities.

Endnotes

1. See, e.g., Madeline Morcelle, *Homelessness Is a Health Justice Issue*, NETWORK FOR PUB. HEALTH L. (March 1, 2018), https://www.networkforphl.org/the_network_blog/2018/03/01/977/homelessness_is_a_health_justice_issue/.
2. Margot Kushel et al., *Factors associated with the health care utilization of homeless persons*, 285(2) J. AM. MED. ASS'N, 200–206 (2001).
3. See, e.g., *Homelessness, Health & Medical-Legal Partnerships*, NAT'L CTR. FOR MEDICAL-LEGAL PARTNERSHIP & NAT'L HEALTH CARE FOR THE HOMELESS COUNCIL, 1–6, 2 (Oct. 2018), available at <https://medical-legalpartnership.org/wp-content/uploads/2018/10/Homelessness-Health-and-Medical-Legal-Partnerships.pdf>.
4. *The Gap: A Shortage of Affordable Rental Homes*, NAT'L LOW INCOME HOUS. COAL., <https://nlihc.org/gap> (last visited Oct. 10, 2018).
5. *2017 Annual Homelessness Assessment Report to Congress*, U.S. DEP'T OF HOUS. & URBAN DEV. (Dec. 2017), available at <https://www.hudexchange.info/resources/documents/2017-AHAR-Part-1.pdf>.
6. *America's Rental Housing—Evolving Markets and Needs*, JOINT CTR. FOR HOUSING STUDIES OF HARV. U. (2017), available at http://www.jchs.harvard.edu/sites/default/files/ahr2013_01-intro.pdf; see e.g., *President's Budget Calls for Drastic Cuts to Affordable Housing*, NAT'L LOW INCOME HOUS. COAL. (Feb. 13, 2018), <https://nlihc.org/article/presidents-budget-calls-drastic-cuts-affordable-housing>.
7. See, e.g., A.B. 1618, Gen. Assemb., Reg. Sess. (Cal. 2016); *Council approves \$25 million affordable housing bond for November ballot*, ARIZ. DAILY SUN (Jun. 14, 2018), https://azdailysun.com/news/council-approves-million-affordable-housing-bond-for-november-ballot/article_e9eb19e6-191c-50cb-ad9c-f1eafc2cdb55.html.
8. See, e.g., *Provisions Respecting Inapplicability and Waiver of Certain Requirements of this Title*, 42 U.S.C. § 1396n(c)(1) (prohibiting the use of Sec. 1915(c) waivers to pay for beneficiaries' room and board).
9. Vikki Wachino, *Coverage of Housing-Related Activities and Services for Individuals with Disabilities*, CTRS FOR MEDICARE & MEDICAID SERV'S (June 26, 2015), <https://www.medicare.gov/federal-policy-guidance/downloads/cib-06-26-2015.pdf> (recognizing the following authorities as opportunities to cover housing-related supportive services: Section 1915(c) Home and Community-based Services (HCBS) waivers; Section 1915(i) HCBS state plan optional benefit; Section 1115 demonstration waivers; Section 1915(b) waivers; Section 1915(k) Community First Choice (CFC) state plan optional benefit; Money Follows the Person (MFP) Rebalancing Demonstration grant dollars; and state plan Targeted Case Management (TCM) Services).
10. *Accountable Health Communities Model*, CTRS FOR MEDICARE & MEDICAID SERV'S, <https://innovation.cms.gov/initiatives/ahcm/> (last visited Dec. 3, 2018).
11. Julia Paradise and Donna Cohen Ross, *Linking Medicaid and Supportive Housing: Opportunities and On-the-Ground Examples*, KAISER FAM. FOUND. (Jan. 27, 2017), <https://www.kff.org/medicaid/issue-brief/linking-medicare-and-supportive-housing-opportunities-and-on-the-ground-examples>.
12. *Medicaid and Supportive Housing*, THE SUPPORTIVE HOUS. NETWORK OF NY, <https://shnny.org/budget-policy/state/medicaid-redesign/> (last visited Dec. 10, 2018).
13. See *Redesigning New York's Medicaid Program*, NY DEPT. OF HEALTH, https://www.health.ny.gov/health_care/medicaid/redesign/ (last visited Dec. 10, 2018); *Integrating Housing in State Medicaid Policy*, CORP. FOR SUPPORTIVE HOUS. (Apr. 2014), https://www.csh.org/wp-content/uploads/2014/04/State_Health_Reform_Summary.pdf (finding that NY originally proposed in its waiver application to use monies from a federal portion of cost savings for supportive housing and capital costs, but CMS denied the proposal).
14. See *MRT Supportive Housing Evaluation*, NY DEPT. OF HEALTH, https://www.health.ny.gov/health_care/medicaid/redesign/2017/shi_overview.htm (last visited Dec. 10, 2018).
15. <https://www.bostonglobe.com/news/nation/2017/01/26/hawaii-bill-would-classify-homelessness-medical-condition/omSQyoeT0M7AUcvR9lt4nL/story.html>.
16. See, e.g., *Homelessness, Health & Medical-Legal Partnerships*, NAT'L Ctr. for Medical-Legal Partnership & Nat'l Health Care for the Homeless Council, 1–6, 2 (Oct. 2018), available at <https://medical-legalpartnership.org/wp-content/uploads/2018/10/Homelessness-Health-and-Medical-Legal-Partnerships.pdf>.
17. Randy Retkin & Maria Campigotto, *The Long Road to State Endorsement of Medical-Legal Partnerships in New York*, Clearinghouse Community (May 2014), <http://povertylaw.org/clearinghouse/stories/retkin>.
18. S.B. 352/AP, 152nd Gen. Assemb., Reg. Sess. (Ga. 2014), available at <https://medical-legalpartnership.org/wp-content/uploads/2014/05/SB-352.pdf>.
19. Cal. Medi-Cal 2020 Demonstration (11-W-00193/9, CTRS FOR MEDICARE & MEDICAID SERV'S (Jun. 1, 2017), available at <https://www.dhcs.ca.gov/provgovpart/documents/medical2020stcs06-01-17.pdf>.
20. *Whole Person Care—Los Angeles Medical/Legal Partnership*, LOS ANGELES COUNTY DEP'T OF HEALTH SERVS., http://dhs.lacounty.gov/wps/portal/dhs!/ut/p/b1/04_Sj9Q1tzA1NjIwtDTSj9CPykssy0xPLMnMz0vMAfGjzOLdDAwM3P2dgo0MTE3MDBy9QkNC3IMsDPxNzYEkIpEVWJj6ORk4GpiY-lt4mBg6mxoQ0h-uH4WqBN0EU0IKDKAKDHAArWn9P4_83FT9-3KgcS88sE0UAMMk-Bw!!/dl4/d5/2dJQSEvUU3QS80SmtFL1o2X0YwMDBHT0JTMjg1TkYwQVYwN0tGMUEwT0sy/ (last visited Dec. 7, 2018); *Health-Center Based Medical-Legal Partnerships, Where they Are, How They Work, and How They Are Funded*, NAT'L CTR. FOR MEDICAL-LEGAL PARTNERSHIP (Jan. 2018), <https://medical-legalpartnership.org/wp-content/uploads/2017/12/Health-Center-based-Medical-Legal-Partnerships.pdf>.
21. *Medicaid Managed Care Request for Proposal for Medicaid Managed Care Prepaid Health Plan (RFP 30-19029-DHB), Addendum 1—Scope of Services*, N.C. DEP'T OF HEALTH & HUMAN SERVS., Aug. 9, 2018, available at <https://www.ncdhhs.gov/request-information>.
22. Pankaj Bhanot, *Amendment to the Hawaii Quest Expanded Medicaid Section 1115 Demonstration (11-W-00001/9)*, STATE OF HAWAII DEP'T OF HUMAN SERVS. (Aug. 29, 2017), available at <https://www.medicare.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/hi/hi-quest-expanded-pa.pdf>.
23. Alex M. Azar II, Remarks at the Hatch Foundation for Civility and Solutions: The Root of the Problem: America's Social Determinants of Health (Nov. 14, 2018), transcript available at <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/the-root-of-the-problem-americas-social-determinants-of-health.html>.

Health Information Technology and Vulnerable Populations: An Overview of Current Policies

By Veda Collmer

Introduction

Vulnerable populations (e.g., individuals with chronic illness, disability, incarceration) experience poorer overall health due to non-medical factors. Non-medical factors, or Social Determinants of Health (SDOH), affecting vulnerable populations, can include low income, unstable housing, and limited education and literacy. SDOH may account for more than 50 percent of health outcomes.¹

Effective health care for vulnerable populations must extend beyond the traditional fee-for-service physician visit to address SDOH. However, treating the non-medical factors impacting health requires an understanding of vulnerable populations, access to social agencies to provide housing and other assistance, improved care coordination, and adequate health literacy programs for patient management of chronic diseases.² The U.S. health care system is on the brink of developing more effective approaches to treating vulnerable populations. Both state and federal governments are shifting payment paradigms from volume-based care to value-based models to address the Triple Aim goals of improving the individual experience of care, improving the health of populations, and reducing the per capita costs of care for populations.³

One component of new health care models focuses on the adoption and effective use of electronic health records (EHRs) and other Health Information Technology (HIT) throughout U.S. health care systems. HIT can improve the health of vulnerable populations by adequately addressing SDOH.⁴ However, effective use of HIT requires financial and technology resources and provider training, as well as altered workflows and connections to other HIT systems. Health care providers serving vulnerable populations often do not have the resources and time to effectively implement HIT to address the unique needs of their patients. This article provides an overview of current U.S. and New York initiatives to promote adoption and connectivity of HIT, as well as identifies policies gaps for improving the health outcomes of vulnerable populations with HIT.

EHR Evolution and the Future of HIT for Improving Population Health

The Department of Health and Human Services (HHS) launched its Healthy People 2020 initiative nearly ten years ago with a mission to shift the health care payment paradigm from costly, episodic physician visits to outcome-driven approaches focused on improving popu-

lation health. This expansive view of health care requires a better understanding of the SDOH. Such a broad perspective can only be achieved through data analytics of individual treatment approaches, predictions about future care models, and the creation of quality standards.⁵ Therefore, EHR adoption throughout the U.S. health care system is necessary for creation of electronic health data to achieve the objectives set forth in Healthy People 2020.

The EHR is defined as a medical record or health care system that is either all or partially electronic. A certified EHR meets certain requirements set forth by the HHS Office of National Coordinator for Health Information Technology (ONC).⁶ Health records should include information impacting patients beyond episodic medical encounters, such as lifestyle information, for delivery of effective care.⁷ In order to create a more expansive picture of the patient, the Institute of Medicine advocated for a shift from paper-based health records to electronic health records to facilitate improved clinical decision-making and better care coordination.

EHRs have evolved over time from limited use by a small number of providers to vendor-created systems and massive adoption in a variety of settings. In the early 1990s, EHRs were mostly used in academic settings, consisted of hybrid paper and electronic systems, and were primarily based around billing and scheduling with some interoperability with other systems. Currently, vendor-developed EHRs are used in a variety of settings (e.g., primary care practices, nursing homes, and hospitals) for clinical decision making, data mapping, data aggregation, billing, and care coordination.

HHS' overall goal for HIT is to create a nationwide infrastructure of connected HIT systems, called a health learning system, to better understand SDOH, improve the quality of health care, and reduce health care costs. Studies have established that EHRs can improve quality of health care for vulnerable populations by addressing SDOH. HIT can enable sharing of knowledge of individual treatments, as well as provide predictive data analytics for the creation of quality standards.⁸ Connected systems sharing standardized data about vulnerable populations can improve coordination of care and inform clinical decision making. Furthermore, electronic health data can be used to guide

VEDA COLLMER is the Chief Compliance Officer and in-house legal counsel for WebPT.

policy and public health initiatives to improve health care for vulnerable populations.⁹

However, while EHRs and HIT are becoming a ubiquitous part of most health care entities, additional policies are needed to incentivize adoption of EHRs across practice settings serving vulnerable populations, as well as mandate IT and other resources to facilitate interoperability for these types of health care providers. Furthermore, tracking SDOH is different from treating traditional medical problems. Currently, there are limited HIT tools available for identifying, documenting, and tracking SDOH in the EHR. Additionally, most providers have not developed the necessary workflows (e.g., patient screening to address social needs, referral resources for community supports, follow up to ensure patient received the resource) and interoperability with social services organization to adequately address SDOH.¹⁰

Current Policies for Promoting HIT to Improve the Health of Vulnerable Populations

Policies Incentivizing Adoption and Meaningful Use of EHRs

Acquiring and implementing EHRs and other HIT into a health care practice is a complicated and expensive project. Purchasing an HIT solution requires analysis of the best EHR for the setting, financial resources for hardware and software purchases and other support services, and some level of information technology expertise in order to operationalize the technology. Proper use of EHRs and HIT often include provider training on using the technology, improving workflows to successfully incorporate the technology, and implementation of methods for patient access to records.

Various incentive programs have facilitated the adoption of EHRs. The federal Health Information Technology for Economic and Clinical Health (HITECH) Act, passed in 2009, created financial incentives for certain providers, known as Eligible Professionals, to adopt and use certified EHRs in their practice. The Medicare Meaningful Use Program, which delivered on HITECH's incentive program, was administered in three stages, beginning with the electronic capture of health data and progressing to other activities, such as increasing patient engagement and improving patient access to electronic health records.¹¹ The Medicaid Meaningful Use Program, administered by the states, applied to more EPs and offered higher financial incentives. Another incentive program, the Primary Care Information Project, implemented in 2005 by the New York City Department of Health and Mental Hygiene, provided subsidized EHRs and two years of technical assistance for primary care practices in underserved areas of New York City.

However, existing policies paying incentives and promoting meaningful use are insufficient to encourage HIT adoption for many providers serving vulnerable populations. First, some providers serving vulnerable populations, such as social workers, behavioral health practitioners, and occupational therapists, do not qualify for state and federal incentive programs. Second, electronic medical records, while more affordable for providers serving vulnerable populations, are not certified by the ONC and, therefore, do not qualify for incentives. Third, financial assistance for EHR adoption must also be accompanied by technical support to ensure meaningful use. EHR adoption alone is insufficient to improve quality of care; rather physicians who receive high levels of technical support demonstrate improved quality of care.¹² Thus, to encourage meaningful use of EHRs for vulnerable populations, existing policies must be expanded to encompass additional providers, encourage ONC certification, and deliver adequate technical assistance.

Policies Transforming Health Care Coverage and Payment Models

The fee-for-service reimbursement model did not pay providers for addressing the SDOH of vulnerable populations. Therefore, providers focused primarily on reimbursable visits and procedures, and mostly ignored SDOH. In 2008, the Triple Aim goals began to establish a framework for improving health care through better care, improving population health, and reducing costs.¹³ An Institute of Medicine Report established the six dimensions of quality care as safety, effectiveness, patient-centeredness, timeliness, efficiency and equity.¹⁴ Several years later, the Patient Protection and Affordable Care Act expanded insurance coverage to millions of low and modest income individuals. The landscape of health care—how providers interacted with patients, how services were reimbursed, and accountability for health outcomes—began to change.

Gradually, public and private payers are replacing the fee-for-service model with new, more expansive payment models that hold providers financially accountable for health outcomes and treatment costs. Both Medicaid and Medicare are attempting to expand the scope of health care services beyond the physician visit to other areas of life affecting patients, as well as require the provider to share responsibility in the patient's recovery. Therefore, providers are now incentivized to consider the SDOH affecting vulnerable populations in the scope of care.

However, integrating SDOH considerations into the health care setting requires more than recording it in the EHR. EHRs must also connect with social services systems (e.g., housing assistance, food resources, Medical-Legal Partnerships) to address SDOH. Providers must collaborate with IT support or EHR vendors to create workflows

and fields in the EHR for triggering assessment (e.g., questions inquiring about housing needs and food insecurity) and planning to mitigate the SDOH affecting vulnerable populations. Policymakers must continue to re-evaluate the effectiveness of emerging payment models, using aggregated data generated from HIT, and adjust incentives or penalties as needed to ensure the health statuses of vulnerable populations are not ignored.

Policies Promoting Interoperability

Federal and state policies have begun to shift focus from EHR adoption to medical data exchange through interoperability. Health information exchange is defined as the electronic movement of health-related information among organizations.¹⁵ Interoperability is defined as the exchange of electronic health information and use of other electronic health information technology without special effort on the part of the user.¹⁶ Interoperability improves care coordination and reduces expensive inefficiencies, such as duplicate tests. Federal initiatives are focused on nationwide interoperability to create a health learning system that will improve clinical decision making and public health. However, developing such a system requires accessible medical data and sharing among different systems, as well as of a consistent quality and format for data aggregation and analytics.¹⁷

Several federal and state policies have begun to pave the foundation for interoperability of this scale. The HITECH Act sought to advance interoperability by strengthening privacy and security protections established by the Health Insurance Portability and Accountability Act (HIPAA).¹⁸ The 21st Century Cures Act, enacted in 2016, further advances interoperability by amending HITECH to require HHS to reduce regulatory or administrative burdens related to the use of EHRs.¹⁹ The Act further advances interoperability by prohibiting information blocking by HIT developers, defined as preventing, discouraging or interfering with the access, exchange, or use of information.²⁰ Lastly, the Act requires ONC to report on priority use of HIT, as well as develop standards and implementation specifications that support the exchange of electronic patient data. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created the Quality Payment Program, which includes the Merit Based Incentive Payment System (MIPS).²¹ MIPS consists of four reporting measures, one of which is the Promoting Interoperability category. The Meaningful Use Program was incorporated into Promoting Interoperability Category and requires use of certified EHRs to exchange health data with other providers and patient.

New York has also implemented policies for interoperability. The State Health Information Network for New York (SHIN-NY), operated by the New York eHealth Collaborative (NYeC), is New York's health informa-

tion exchange. SHIN-NY's objectives include improved patient access to records and enhanced care coordination. Through SHIN-NY, patient records are shared securely among eight Qualified Entities (QEs) statewide. QEs must satisfy certain security, technical, and contractual requirements to connect with SHIN-NY.²² NYeC's 2020 roadmap includes interoperability and health information exchange across the state for providers, health plans and public health.²³ Currently participation in SHIN-NY is strong for hospitals, Federally Qualified Health Centers and public health departments, but not for physician practices, home care agencies, nursing homes, and behavioral health providers. NYeC plans to further facilitate interoperability by addressing barriers, such as vendor adherence to national interoperable common clinical dataset standards (CCD/C-CDA), lack of certified EHRs in some specialties (e.g., long-term care and behavioral health), and vendor participation in HIE hubs.²⁴ The Health Care Efficiency and Affordability Law for New Yorkers (HEAL NY) was a data exchange incentive program that funded the development of Regional Health Information Exchanges (RHIOs) in order to develop the interoperability framework for SHIN-NY. HEAL NY provided a substantial investment for the development of a statewide health information exchange.

While health data exchange is occurring, federal and state policies have much ground to cover to improve health care for vulnerable populations through HIT. Policies that provide financial assistance and technical support are needed to encourage physician practices and ambulatory centers serving vulnerable populations to develop interoperability capacity. Policies must address the financial sustainability and technical support challenges of maintaining interoperable HIT.²⁵ Providers must agree to follow established data sharing practices, either as mandated by law or contractually, to protect the privacy of vulnerable populations. Policies must also require industry wide testing and HIT certification to encourage participation in SHIN-NY, which includes adherence to consistent quality and security measures. Lastly, structured data requirements should identify ways SDOH can be collected to assist providers with prioritizing the highest impact issues. For example, ONC's proposed rule replaces current structured standards with the United States Core Data for Interoperability (USCDI) for improving data exchange. ONC implemented the change to address more data classes, such as SDOH. Data collected and exchanged in accordance with USCDI can enhance provider intervention through improved collaboration with ancillary services and referrals to community programs.²⁶

Policies Promoting Patient Engagement

Interoperability will enable vulnerable populations to become actively engaged in their own care. Patients who are actively engaged in their health care, including par-

ticipation in the decisions about their health care, demonstrate improved outcomes. Patient engagement requires access to health information through patient portals (websites connected to EHRs that grant patient access to medical records), receipt of health educational materials, self-generated data, and patient experience. With the shift from fee-for-service reimbursement to value-based payment models, federal policies have promoted patient engagement as a critical component of quality care. EHRs have the capacity to promote patient engagement by enabling access to health materials and records via the patient portal and other technology and connecting with remote monitoring technology.²⁷

New resources are emerging to provide patient access to their health data. The MyHealthEData initiative, launched in March 2018, allows Medicare beneficiaries to download their health data. The Blue Button 2.0 initiative allows patients to securely download patient records to share with doctors. The Center for Medicare and Medicaid Services Meaningful Measures framework is a new project to identify the priorities for measuring quality improvement. One component of Meaningful Measures facilitates effective physician-patient communication and coordination of care, including transfer of health information and interoperability.²⁸ MIPS penalizes or incentivizes providers based on, among other activities, patient access to real time data, portability of health records, and the ability to communicate securely with patients. Access to health records and engagement in care decisions can significantly improve health care for vulnerable populations.

Policies Facilitating Patient Privacy

Exchanging data within a health information exchange must include safeguards to ensure only authorized providers have access to necessary patient information to best inform treatment planning. In the age of massive privacy breaches and news stories of gross misuse of personal information, ensuring patient privacy is a crucial component of interoperability and EHR adoption. However, the current state of patient privacy protections involves a patchwork of overlapping state and federal laws. Most health care providers do not understand the restrictions placed on patient health records, which laws apply to different types of patient information, and who can share patient data. Therefore, many providers are reluctant to share data to avoid HIPAA and other violations.²⁹

Sharing patient data with authorized users is an essential component of care coordination, improved clinical decision making, and predictive analytics benefiting vulnerable populations. Furthermore, vulnerable populations receive care from a variety of health care providers and social services agencies, so compiling patient health

information in one central location can capture a complete view of the patient's needs. Coordinated care and sharing of data through different EHRs and other systems will improve care for vulnerable populations. EHRs and HIT can also protect certain health information, such as substance use disorder information, through technical safeguards to ensure patient privacy.

Policy makers have begun to address the barriers to data exchange with new regulations to encourage protected health data sharing. Medicare's Meaningful Use program sought to expand health information data exchange through promotion and adoption of ONC-certified technologies to support secure care and interoperable health information exchange.³⁰ The Medicare Physician Fee Schedule Final rule, implemented in October 2018, mandates some eligible providers submit surveillance data to public health agencies.³¹ To further facilitate data sharing, the Office for Civil Rights is seeking public input on ways the HIPAA rules can be modified to promote care coordination and data sharing.³²

Similar policies to the EU General Data Protection Regulation (GDPR) are also needed to prioritize patient ownership of their health care data, rather than a secondary consideration to state and national data exchange.³³ Policies are needed to establish standards to protect health and equality above commercial interest in data use. Since SDOH and health disparities affect minorities and the elderly, predictive modeling has the potential to intrude on privacy and autonomy and possibly stigmatize some groups. Strong privacy policies and enforcement, as well as transparency regarding data access, will establish trust that data is exchanged with authorized users for the purposes of improving care.³⁴

Policies Mandating Information Security and Certification for EHRs

Creating a secure network of HIT systems where health information can be shared with only authorized users and protected from unauthorized access or alteration is a critical component of EHR adoption and interoperability. Health care entities have increasingly become a target of cybercrime as more entities adopt EHRs. Larger health care entities have the resources and expertise to understand and mitigate information security risk, whereas small practices often have limited resources to protect their systems. Connecting different EHRs into a larger network exposes other systems to information security risks.

HITECH mandates enhanced privacy and security protection for protected health information to foster trust in the use, creation and transmission of protected health information.³⁵ ONC was tasked with an electronic health records certification framework, which includes such security measures as authentication and encryption standards.

The 21st Century Cures Act mandated ONC to develop a framework and agreement for the secure exchange of health information to facilitate interoperability. ONC's framework includes requirements for the secure exchange of health information, development of a framework and agreement for secure exchange of health information between networks, and publication of the networks that adopt the agreement.³⁶ New requirements for SHIN-NY include EHR certification by a NYS DOH approved certification body (e.g., HITRUST), incident response reporting to the NYeC CISO, development and implementation of organizational cybersecurity policies and procedures, and cybersecurity insurance.³⁷

While information security is an important component of protecting health records, additional certification requirements, insurance coverage, and risk management standards may be a barrier to EHR adoption and interoperability for health care providers serving vulnerable populations. EHRs certified by ONC are significantly more expensive and only certain providers (e.g., physicians, chiropractors, dentists, optometrists, podiatrists) qualify for Meaningful Use Incentives. Smaller physician practices in underserved areas often do not have the resources in time, money or expertise to develop a risk management strategy or purchase cybersecurity insurance.

Resources are available through the ONC, NYeC, and other federal and state entities for securing protected health information. However, free resources will not bridge the gap for small physician practices and other providers serving vulnerable populations. Policies ensuring dedicated information technology and security resources are necessary to facilitate participation in SHIN-NY, as well as secure adoption of HIT. Policies are also needed to provide EHR incentives for other health care providers, such as social workers, behavioral health specialists, and rehabilitation providers, to enable adoption of certified EHRs and participation in HIEs.

Conclusion

Federal and state goals to create a national health learning system for seamless data exchange, improved clinical decision making, and predictive analytics will significantly benefit vulnerable populations. Adoption of interoperable HIT can improve care coordination, address the SDOH impacting vulnerable populations, and improve patient engagement. However, additional policies are needed to address the unique needs health care providers serving vulnerable populations.

Endnotes

1. About social determinants of health, World Health Organization (2017), https://www.who.int/social_determinants/sdh_definition/en/ (last visited Jan 10, 2019).

2. Nicole L. Friedman & Matthew P. Banegas, *Toward Addressing Social Determinants of Health: A Health Care Strategy*, 22 *The Permanente Journal* (2018), <http://www.thepermanentejournal.org/issues/2018/volume-22-suppl-issue/6889-social-determinants-of-healthcare.html> (last visited Jan 10, 2019).
3. Donald M. Berwick, Thomas W. Nolan & John Whittington, *The Triple Aim: Care, Health, and Cost*, 27 *Health Affairs* 759–769 (2008).
4. Michelle Martelle et al., *Meaningful Use of an Electronic Health Record in the New York City Jail System*, 105 *American Journal of Public Health* 1752–1754 (2015); Andrew M. Ryan et al., *Small Physician Practices in New York Needed Sustained Help To Realize Gains In Quality From Use of Electronic Health Records*, 32 *Health Affairs*, 53–62 (2013).
5. Janine S. Hiller, *Healthy Predictions? Questions for Data Analytics in Health Care*, 53 *American Business Law Journal*, 251–314, 261 (2016).
6. Meaningful Use and MACRA, HealthIT.gov, <https://www.healthit.gov/topic/meaningful-use-and-macra/meaningful-use-and-macra> (last visited Jan 10, 2019).
7. R.S. Evans, *Electronic Health Records: Then, Now, and in the Future*, IMIA Yearbook of Medical Informatics 2016, 2016, at 48–60.
8. Hiller, *supra* note 5 at 261.
9. Rachel Gold et al., *Adoption of Social Determinants of Health EHR Tools by Community Health Centers*, 16 *The Annals of Family Medicine* 399–407 (2018).
10. *Id.* at 403.
11. Meaningful Use Objectives and Measures for Eps, Eligible Hospitals, and CAHs for 2015 through 2018, § 495.22 (2017).
12. Ryan, *supra* note 4 at 8.
13. Berwick, *supra* note 3 at 780.
14. *Id.*
15. Lisa M. Kern et al., *HEAL NY: Promoting Interoperable Health Information Technology In New York State*, 28 *Health Affairs* 493–504 (2009).
16. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019, Fed. Reg. vol. 83, 226, 59720 (Nov. 23, 2018).
17. Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf> (last visited Jan 9, 2019).
18. HITECH 5568, 78 FR 5565, <https://www.federalregister.gov/documents/2013/01/25/2013-01073/modifications-to-the-hipaa-privacy-security-enforcement-and-breach-notification-rules-under-the#p-615>
19. 21st Century Cures Act, Pub. L. No. 114-255, § 4003 (2016)
20. 21st Century Cures Act, Pub. L. No. 114-255, § 4002 (2016)
21. Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. § 1305 (2015).
22. Minimum Service Requirements Qualified Entity Minimum Technical Requirements, 10 N.Y.C.R.R. 300 (b)(3)(Apr. 2018)
23. 2020 Roadmap: Improving Health in Our Communities, 2020 Roadmap: Improving Health in Our Communities, <https://www.nyehealth.org/shin-ny/2020-roadmap/> (last visited Jan 11, 2019).
24. *Id.*; Minimum Service Requirements Qualified Entity Minimum Technical Requirements, 10 N.Y.C.R.R. 300 (b)(3)(Apr. 2018).

PUBLIC HEALTH LAW AND VULNERABLE POPULATIONS

25. See Ryan, *supra* note 4.
26. 45 CFR 170 and 171, 3/4/2019, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.
27. *A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure, a 10-Year Vision to Achieve an Interoperable Health IT Infrastructure*, <https://www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf> (last visited Jan 12, 2019).
28. 42 CFR § 412, 38591 Medicare Program; FY 2019 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for Fiscal Year Beginning October 1, 2018, 83 Fed. Reg. 151, 38951 (Aug. 6, 2018) (codified at 42 CFR 412).
29. Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 Fed. Reg. 240, 63404 (Dec. 14, 2018).
30. 42 CFR § 412, 10/1/2014, 45966 Medicare and Medicaid Programs: Electronic Health Record Incentive Program, 42 CFR §412, 413, 422, 495 (2010); Health Information Technology Standards, 42 C.F.R. §170 (2012); 2015 Edition Health Information Technology Certification, 45 C.F.R. §170 (2015).
31. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule And Other Revisions to Part B for CY 2019, Fed Reg. vol. 83, 226, 60096 (Nov. 23, 2018).
32. Request for Information on Modifying HIPAA Rules to Improve Coordinated Care Request for Information on Modifying HIPAA Rules to Improve Coordinated Care, 83 Fed. Reg. 240, 63404 (Dec. 14, 2018).
33. Hiller, *supra* note 5 at 309.
34. *Id.*
35. Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat.231.
36. 21st Century Cures Act, Pub. L. No. 114-255, § 4003-4004 (2016).
37. NYeC Staff, Summary of Changes to Version 3.5 of the SHIN-NY Privacy and Security Policies and Procedures for QEs and their Participants New York eHealth Collaborative(2018), <https://www.nyehealth.org/shin-ny-pp-changes-april-2018/> (last visited Jan 13, 2019).

NEW YORK STATE BAR ASSOCIATION

“Pro Bono in Your PJs”

**Log onto
NY.freelegalanswers.org
and sign up to be a
volunteer today!**

Questions?

Contact Thomas Richards
Director, Pro Bono Services, NYSBA
trichards@nysba.org | 518.487.5640



The Palliative Turn in Person-Centered Care: Public Health and Human Rights-Based Approaches to Interdisciplinary Palliative Care

By Mary Beth Morrissey, Thomas Caprio and Cary Reid

Introduction

Palliative care is a type of care that focuses on improving quality of life in patients with advanced illness and their family members. Patients who receive palliative care experience improved quality of life,^{1,2,3,4,5} fewer depressive symptoms,^{1,3,5} decreased emergency room visits and hospital admissions,^{6,7,8} as well as higher levels of satisfaction with care.⁴ There has been incremental progress in the growth of palliative care across the care continuum at both federal and state levels. New York, for example, has been a leader in palliative care at the state level, enacting two laws⁹ that establish a right to palliative care for New Yorkers. However, more progress needs to be made, especially in bridging geriatrics and palliative care and in building community-based palliative care. The direction in palliative care is toward population health management and design of population-level interventions, including primary care and community-based interventions that offer a public health response to suffering and improve quality of life. The shift from palliative medicine to palliative systems of care that integrate specialized medical care and socially directed supportive care¹⁰ will be key to the future of U.S. health care in advancing what is being called a *palliative turn*¹¹ in the provision of person-centered health services, that is, embedding the palliative approach to care across all levels of the aging and health systems and society—from hospital to community.

Human Rights Frameworks: The Right to Health

Palliative care is situated in a human rights paradigm. The nexus of health and human rights and their mutual and interdependent character within the larger human rights paradigm was recognized in the early 1990s by Jonathan Mann and colleagues.¹² There is a range of possibilities in the progressive realization of health and human rights. For example, health itself as a human right may serve to support and reinforce other human rights, such as the right to water, sanitation, food, housing, education and transportation, or in the alternate, marginalization of the right to health through regressive health policy that may interfere with the full realization of such human rights. Conversely, burdens on human rights may compromise access to and achievement of health. Thus, health is not merely a biomedical and biocapital production of medical facilities and health systems, but rather

is advanced through environmental conditions that make possible its full realization. A paradigmatic example of the right to health and human rights interaction is seen in the relationship between education and health. Olshansky and colleagues¹³ have mapped the impact of race and education on life expectancy in the United States and identify an education-health-longevity gradient, as well as widening gaps in life expectancy demarcated by educational level and racial group membership.

In 2000, the United Nations Committee on Economic, Social and Cultural Rights adopted General Comment No. 14 (“Comment 14”).¹⁴ Comment 14 recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,¹⁵ and provides authoritative guidance on the right to health, framed as, “a right to an effective and integrated health system, encompassing health care and the underlying determinants of health, which is responsive to national and local priorities, and accessible to all.”¹⁶ Broader than “health care,” the right to health requires assurances of effective and accessible health systems, and the right to freedom from interference, for example, in torture or non-consensual medical treatment and experimentation.¹⁷

The Right to Palliative Care and Pain Relief

Comment 14 spells out the normative content of the right to health, inclusive of rights to palliative care and pain management: availability, accessibility, ethical and cultural acceptability, quality and the non-discriminatory provision of health facilities, goods and services.¹⁸ The Global Palliative Care Atlas¹⁹ clarifies further that while Comment 14 contains no express reference to palliative care, it explicates the normative content of the right to health and specifies the core obligations of all signatory nations without regard to nations’ resources, which include: “access to health facilities, provision of goods and services on a nondiscriminatory basis, the provision of essential medicines as defined by the WHO, and the adoption and implementation of a public health strategy.”²⁰ Nation states are not relieved of the obligation to operationalize the right to health under international law even in the absence of a constitutional right to health care, such as in the United States. The U.N. Special Rapporteur on torture has stated that “denying access to pain relief can amount to inhuman and degrading treatment.”²¹

In 2010, delegates to the International Pain Summit of the International Association for the Study of Pain voted to support the Montreal Declaration,²² a policy statement explicitly declaring and recognizing the right to pain management as a fundamental human right.

International Palliative Care Frameworks and Recommendations

The WHO definition of palliative care frames the goals of palliative care and provides a description of palliative care services:

Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.²³

The Public Health Strategy (PHS) for Palliative Care builds on the WHO definition, and advances a robust agenda for translating knowledge, evidence and innovation into effective population-level interventions and practices for relieving suffering and improving quality of life for persons with illness and serious illness across the life span. The PHS encompasses four key components: Formulation of national policies and regulations, including development of funding sources and service delivery models; 2) Assuring adequate drug availability, including access to essential medicines, and addressing costs, prescribing, distribution, dispensing and administration; 3) Provision of education and training for all health care and community health workers and members of the public; and 4) Effective implementation of policy through strategic business plans, infrastructure, standards and guidelines.²⁴

More recently, the WHO's adoption of Resolution WHA 67.19,²⁵ *Strengthening of palliative care as a component of comprehensive care throughout the life course*, marked a milestone in the realization of palliative care as a right. WHO's Ad Hoc Technical Advisory Panel on Palliative Care overseeing the implementation of the Resolution developed a Program Operations Manual²⁶ ("Manual") that provides a blueprint for mapping out and implementing palliative care programs and best practices on the ground. The Manual expands on the WHO definition of palliative care:

Palliative care is the prevention and relief of suffering of any kind—physical, psychological, social, or spiritual—experienced by adults and children living with

life-limiting health problems. It promotes dignity, quality of life and adjustment to progressive illnesses, using best available evidence...All people, irrespective of income, disease type, or age, should have access to a nationally determined set of basic health services, including palliative care. Financial and social protection systems need to take into account the human right to palliative care for poor and marginalized population groups.²⁷

In a recently released groundbreaking and visionary report on palliative care, the Lancet Commission²⁸ calls attention to the moral failing of the global public health systems in the face of extreme suffering, unrelieved pain, poverty and inequity across the world, especially in low- and middle-income countries. The Commission calls for worldwide recognition of palliative care and pain relief as essential components of universal health coverage and social provision, and progressive realization of these goals.

The Lancet Commission Report focuses primarily on palliative care health-related interventions in the context of end-of-life, life-threatening or life-limiting illness or conditions. The Commission Report recognizes but expressly excludes palliative care needs that are not related to end-of-life, life threatening or life-limiting illness or conditions. In these contexts, the Commission Report identifies a new measure of suffering called "serious health-related suffering," which is associated with illness or injury and physical, emotional or social suffering and cannot be relieved without medical intervention. The Commission also proposes an essential package of palliative care and pain relief services, resources and interventions that respond to serious-health-related suffering burdens, and recommends social support programs as a complement to this essential package.

Growing Heterogeneity in Palliative Care in the United States

Bridging Geriatrics and Palliative Care

The shifting demographics to an aging population in the U.S. has created an unprecedented challenge to society and to the health care system. The U.S. Census Bureau projects the adult population age 65 and older will exceed 80 million by the year 2050. The fastest growing segment of this older population will be the aged 85 and older, sometimes referred to the "oldest old." This demographic shift in the population will undoubtedly result in utilizing an increasing proportion of health care resources and will require clinicians who are competent in meeting the specific health needs of older adults, especially those with chronic illnesses and those affected by Alzheimer's disease and related dementias. This imperative under-

scores the importance of fields like geriatric medicine and its interface with palliative care, in order to meet the evolving and complex needs of those who are aging with illnesses. Unfortunately, significant workforce gaps currently exist in meeting the needs of older adults with clinicians appropriately trained in geriatrics. The number of board-certified geriatricians (physicians who specialize in geriatric medicine) has steadily declined since the year 2000 despite the increasing proportions of the older adult population with health care needs.²⁹ Additionally, fewer than 1 percent of nurses, pharmacists, and physician assistants specialize in geriatrics and fewer than 4 percent of social workers are geriatrics specialists.³⁰

Geriatrics focuses on teams of interprofessional health care providers who focus on the identification and management of disability, chronic illness, and frailty in older adults, with the overarching goals of maintaining or improving function and enhancing quality of life. These goals overlap significantly with the philosophy of palliative care but also acknowledge the uniqueness of an older adult population, who are often faced with multiple chronic conditions and functional losses that are threats to maintaining independence. The physical and cognitive functioning of a person often defines the level of independence (or alternatively the relative dependency on others for daily care) as well as the personal perception of dignity. Chronic illnesses can also carry a significant physical symptom burden for the individual such as pain, nausea, shortness of breath, depression, or insomnia. This loss of independence and increasing symptom burden may contribute to the perceived suffering by the individual and become ideal targets for palliative interventions to improve the quality of life.

Alzheimer's disease and related dementias are a growing public health crisis and a significant challenge in the delivery of health care and aging services. It is estimated that over 14 million Americans will be living with Alzheimer's disease by 2050.³¹ Disproportionately affecting the older adult population, it is marked by the progressive loss of cognitive abilities and is at present without any known effective treatment or cure. Alzheimer's disease affects a person's functional ability and behaviors as the disease progresses, resulting in increasing dependency on others for care and safety. Ultimately, dementia leads to loss of decision-making capacity for the individual. The need for clear goals of care discussions, advance care planning, and appointment of surrogate decision-makers for those afflicted with dementia is paramount and entirely consistent with the needs for delivery of effective palliative care. In the end stages of the disease, persons often have loss of mobility, difficulty swallowing and maintaining adequate nutritional intake, and are at increased risk for developing pneumonia, pressure ulcers, and requiring institutional-based care.

Not only is effective symptom management needed for these patients with dementia but family and caregiver support is critical to provide anticipatory guidance as to the stages of the disease and to assist in decision-making that supports individual goals of care.

Palliative care at the end of life for older adults is best exemplified through the Medicare Hospice Benefit. This formalized delivery system for high-quality palliative care became part of Medicare in 1982 and remains a key component of Medicare Part A for adults age 65 and older and younger patients with chronic illness and disabilities. The eligibility for hospice care is the determination by two physicians that a person has an expected prognosis of six months or less if the disease follows a typical or expected course. Those who receive hospice services must elect to no longer pursue disease-directed or life-prolonging health care interventions; instead the focus is entirely on palliative goals of care including symptom management, psychosocial support, and spiritual care. Hospice care has been increasingly utilized over time and the composition of patients receiving hospice care has significantly changed, shifting from over 75 percent of patients receiving hospice services for cancer-related diagnoses, to currently more than 70 percent of patients who now receive hospice care for non-cancer diagnoses, including end-stage diseases such as cardiac, lung, liver, and dementia.³² This shift in diagnoses of patients served by hospice reflects the changing demographics of the population with increasing older adults, increasing prevalence of chronic disease (e.g., Alzheimer's disease), and the progress made overall in the diagnosis and treatment of cancers. The Medicare Hospice Benefit provides an interdisciplinary team of professionals experienced with symptom management and end-of-life care including nurses, physicians, social workers, and chaplains. Hospice aides provide hands-on assistance for personal care to those who are significantly debilitated and hospice volunteers provide support and companionship to patients and caregivers. Bereavement services through hospice are provided to families in anticipation of loss and following the death of loved one. Many palliative care programs that have subsequently developed in the U.S. have attempted to include or adapt components of the Hospice model of care in their own work, especially the work of the interdisciplinary team, bereavement programs, spiritual care, and social services.

Community-Based Palliative Care Models

The benefits of delivering palliative care in the hospital setting have been well established and led to the broad diffusion of inpatient palliative care programs throughout the US.³³ However, these programs collectively reach relatively small numbers of individuals with established palliative care needs, prompting efforts to increase the reach

of palliative care programs outside of the hospital setting. New venues for delivering palliative care include outpatient clinics and home-based palliative care programs. Outpatient based palliative care clinics are now appearing in large health systems.³⁴ Staffing shortages and low reimbursement rates for palliative care services delivered as part of this type of care in the outpatient setting constitute key barriers to continued growth of these entities.³² Home-based palliative care programs constitute another vehicle for delivering palliative care outside of the hospital setting. These programs are now well established in many regions of the country and most are staffed by a combination of nurses, nurse practitioners, social workers and physicians. In an effort to quantify the benefits of one home-based palliative care program, researchers conducted a randomized controlled trial to compare in-home delivery of palliative care for patients with advanced illness (versus usual care) and found that patients receiving home-based palliative care had increased satisfaction with their care, greater rates of dying at home (as per their wishes), and demonstrated fewer trips to the emergency room and significant cost savings.³⁵ Other studies evaluating home-based palliative care initiatives have confirmed significant cost savings and improved patient outcomes, including reduced symptom burden and rates of advance directive completion.^{36,37,38} These results have led to increased efforts to develop and implement home-based palliative care programs in diverse health systems. Leaders in this area include various health-maintenance organizations and the Veterans Administration. Other agencies that have explored offering home-based palliative care include hospice and home care agencies. However, reimbursement rates (which are low) for delivery of home-based palliative care services via organizations operating under the fee for service model constitute a key barrier to further program diffusion.

A key barrier to further growth of these programs at the patient level is that individuals with advanced chronic illness who qualify for Medicare hospice benefits (i.e., those with an estimated life expectancy of six months or less) and who elect the hospice benefit must forego receipt of life-prolonging care. This rule is problematic because many older adults with advanced chronic illness desire supportive care but aren't ready to forego life-prolonging therapies. This rule disproportionately affects hospice agencies that provide palliative care services to patients and their families in the last 6 months of life. In recognition of this dilemma, the Centers for Medicare and Medicaid Services (CMS) is currently testing a new model (i.e., Medicare Care Choices Model) that allows individuals to receive supportive care through a hospice agency and continue to receive services provided by other Medicare providers.³⁹ CMS is looking to determine whether this approach, which includes provision of

supportive services in patients' homes, can improve the quality of life and care received by Medicare beneficiaries, increase patient satisfaction, and reduce Medicare expenditures. Primary results from this innovation demonstration project are expected to be reported soon.

This CMS initiative and other efforts are clearly needed to build capacity to address the large palliative care needs of the millions of adults living in the U.S. with advanced chronic illness. Given the continued aging of the U.S. population—the proportion of the population ages 65 and older has grown from 4.1 percent in 1900 to 12.6 percent in 2000 and will be an estimated 20 percent by 2030⁴⁰ and 24 percent by 2060⁴¹—it remains to be seen whether efforts by the health care system to include the extensive network of U.S.-based hospice agencies, which currently number around 4,000, will be sufficient to meet these needs. More than 75 percent of adults 65 and over suffer from at least one chronic medical condition, and 20 percent of Medicare beneficiaries have five or more chronic conditions.^{42,43} Advanced chronic illness is especially prevalent among those ages 85 and older, projected to be the fastest growing cohort of older adults.⁴⁴ Further, due to established health disparities, ethnic and racial minorities are at disproportionate risk for adverse health outcomes over the life course compared with non-Hispanic whites.⁴⁵

Adopting a public health approach to meeting the palliative care needs of an aging society will mandate that community agencies and organizations serving adults with advanced chronic illness participate fully in these efforts.⁴⁶ Two agencies in particular that could play a role include the aging service agency network and faith-based community. Both of these entities have longitudinal relationships with clients/parishioners and their missions are clearly consonant with the goals of palliative care movement, i.e., to enhance the quality of life and dignity of individuals and families served by these entities and in the case of aging service agencies to minimize the risk of institutionalization of those with advanced chronic illness. Finally both entities play a pivotal role in supporting both informal and formal care that gets delivered in the home to individuals with advanced chronic illness.⁴⁴ Examples of efforts by aging service agencies and the faith-based communities to address palliative care needs of the individuals served by these groups are described briefly below.

In New York City, researchers from Cornell University and Hunter College partnered with both aging service and faith-based agencies in Harlem to begin to address the palliative care needs of Harlem-based residents. These efforts included conducting a needs assessment documenting the substantial palliative care needs of individuals served by the participating agencies.⁴⁷ One

of the outcomes of this needs assessment was the realization that assessment tools were needed that could be used by agency staff to identify persons with palliative care needs. The community agency researcher partnership addressed this service gap by developing a palliative care needs screening tool for use by staff working in these settings and demonstrated the feasibility and utility of using the tool in various senior centers throughout New York City.^{48,49} Other work conducted by this partnership includes developing and testing a formal educational curriculum to train case managers caring for homebound older New York City residents about palliative care principles and practices.⁵⁰ The educational curriculum has been successfully piloted with promising results in the form of enhanced knowledge on the part of case managers who participated in the year-long training program and increased receptivity to addressing palliative care needs in the clients served by case managers.⁴⁸ In addition, an Area on Aging Agency in Ohio partnered with a local health system to develop methods to identify palliative care needs and provide palliative care services to adults enrolled in a Medicaid Waivers program. Case managers played a pivotal role in this effort by screening individuals for palliative care needs and helping to implement an intervention that included recommendations provided by a palliative care physician.⁵¹ In a pilot randomized controlled trial, patients randomized to receive the intervention had fewer hospitalizations and nursing home admissions as compared to participants who received usual care.⁴⁹ These promising efforts highlight the role aging service agencies can play in identifying community-dwelling older adults with palliative care needs and in delivering interventions to address those needs.

Efforts underway in the faith-based community include a needs assessment of community-based clergy that identified both a desire and need for further training in meeting the palliative care needs of seriously ill individuals.⁵² A national needs assessment is currently underway as part of the National Clergy Project on End-of-Life Care, which is designed to identify knowledge and training gaps that could be addressed through formal educational interventions to assist clergy in the care of individuals with advanced serious illness.⁵³ Finally, other efforts include a training curriculum for nurses in parishes who then are called upon to address palliative care needs of congregation members.⁵⁴

Another challenge that will need to be addressed is enhanced public awareness about the role palliative care can play in the lives of individuals with advanced chronic illness and their families. Public awareness of palliative care remains poor.⁵⁵ Public health education efforts are needed at the local, state and national level to educate the public about the benefits of this type of care

and are urgently needed to educate the public and palliative care and its associated benefits.^{56,57,58}

Palliative care is well-established in U.S. hospitals and has begun to expand outside of the hospital setting to meet the needs of adults living with advanced chronic illness. However, in order to be maximally effective, the engagement of aging service agencies, the faith-based community and the public health infrastructure are urgently needed to educate the public about the value of palliative care, to expand a workforce with skills to meet these needs and programs and practices that can reach individuals in settings outside of the hospital. Experts have called for the development of innovative community-based models that facilitate delivery of palliative care to affected individuals. Aging service agencies, public health programs at the local, state and national level, and the faith-based community constitute key stakeholders that are ideally positioned to initiate public awareness campaigns, expand a trained workforce, and help in the development, implementation and evaluation of new and promising models of palliative care delivery.

The Four-Prongs of the Public Health Strategy for Palliative Care

In light of the growing diversity in palliative care models and consistent with the public health strategy for palliative care, we call attention to the four-pronged approach to help address the problem of unmet palliative care needs: 1) national policy making; 2) assuring access to essential medicines; 3) education and training for aging and health professionals, including judges and community workers; and 4) policy implementation, including at the systems level.

National-level Policy

Enactment of federal legislation that would create a federal right to palliative care in the United States and provide funding for such programs is a priority, as called for by the Lancet Commission (2017).²⁸ U.S. federal agencies have begun to take incremental steps to address the public health problem of pain, an important focus of palliative care.

National-level policy on palliative care may also be influenced by professional associations and advocacy organizations that have adopted their own policies or resolutions on palliative care, such as the American Public Health Association (Morrissey & Miller, 2013),⁵⁹ the American Heart Association (Braun et al., 2016),⁶⁰ and the American Psychological Association (2017).⁶¹

Availability of Essential Medicines

Federal and state-level policy must assure the availability of essential medicines, such as opioids. On October

PUBLIC HEALTH LAW AND VULNERABLE POPULATIONS

MARY BETH QUARANTA MORRISSEY, Ph.D., MPH, J.D., is a health and social work researcher and New York health care attorney. She holds the appointments of Fellow at Fordham University's Global Healthcare Innovation Management Center, Senior Policy Advisor in Health and Ethics and Aging & Health Workforce Development Institute Director, Finger Lakes Geriatric Education Center, University of Rochester Medical Center. Dr. Morrissey is President of the American Psychological Association Society for Theoretical and Philosophical Psychology; President of the National Committee for the Prevention of Elder Abuse; President of the Collaborative for Palliative Care, New York; Chair of the Westchester County Bar Association Health Law Committee and a current member of the New York State Bar Association Health Law Section, Ethical Issues Committee and Public Health Committee; and past president of the State Society on Aging of New York and the Public Health Association of New York City.

THOMAS CAPRIO, MD, is an Associate Professor of Medicine, Geriatrics, Dentistry, Clinical Nursing, and Public Health Sciences at the University of Rochester (UR) Medical Center in Rochester, New York. He is the Chief Medical Officer of UR Medicine Home Care and the Medical Director for the Visiting Nurse Hospice & Palliative Care. He serves as director of the Finger Lakes Geriatric Education Center and oversees the federally-funded Geriatric Workforce Enhancement Program which provides education and training related to geriatrics, palliative care, and dementia care for health care professionals and family caregivers across New York State. He is a fellow of the American College of Physicians, fellow of the American Geriatrics Society, and Fellow of the American Academy of Hospice and Palliative Medicine.

M. CARRINGTON REID, MD, is an Associate Professor and Director of the Office of Geriatric Research at Weill Cornell Medicine. Dr. Reid's work supports translational research on pain and aging in New York City. Current projects include testing non-pharmacologic strategies for pain among older persons in both clinical and non-clinical settings, identifying barriers to the use of self-management strategies for pain, and examining optimal strategies for managing pain across ethnically diverse populations of older adults. Other areas of interest include the epidemiology and treatment of substance use disorders in older persons. Institutional partners include Cornell University (Ithaca), Weill Cornell, Hebrew Home at Riverdale, Columbia University, Hospital for Special Surgery, Memorial Sloan Kettering, Council of Senior Centers & Service of NYC, Inc. and the Visiting Nurse Service of New York.

The authors wish to acknowledge the assistance of Ivelina V. Popova, Esq., Garson & Jakub, LLP, in editing the manuscript.

26, 2017, the President of the United States declared the opioid crisis in the United States a national public health emergency under federal law. Even in light of the declaration of this national public health emergency, persons with serious illness and chronic pain or intolerable and intractable pain still have a right to access the full range of medicines they need to relieve and control their pain.⁶² The Lancet Commission Report, *Alleviating the access abyss in palliative care and pain relief—an imperative of universal coverage*,²⁸ recognizes the need for balance in assuring both the safe use of opioids and reducing the risks of diversion and conflicts of interest:

The crisis in the USA provides lessons on the need for maximising the benefits of opioids and minimising the risk of non-medical use. Countries should monitor the supply and marketing of opioids and implement strong conflict-of-interest policies to restrict undue influence of all for-profit entities in the tendering, procurement, and marketing of opioid medications and in describing indications for use and prescription of opioid medications. These policies must also guarantee training on safe use of opioid analgesics grounded in evidence-based protocols.²⁸

The 2011 Institute of Medicine Report, *Relieving Pain in America*,⁶³ drew attention to the seriousness and magnitude of the public health problem of pain and the over 100 million adults living with chronic pain. In response to the IOM's recommendation, the Department of Health and Human Services created the Interagency Pain Research Coordinating Committee that coordinated the development of a *National Pain Strategy, a Comprehensive Population Health-Level Strategy for Pain* (NPS).⁶⁴ The NPS addresses six key areas: population research, prevention and care, disparities, service delivery and payment, professional education and training, and public education and communication.

In addition, the National Institutes of Health Office of Pain Policy released its Federal Pain Research Strategy (FPRS),⁶⁵ an effort that was also overseen by the Interagency Pain Research Coordinating Committee. The FPRS is directed to all federal agencies and departments that are involved in pain research.

Education

Strong foundations in geriatrics, palliative, and end-of-life care are needed in the education and training provided to our aging and health professionals and para-professionals in multiple domains, including pain management, ethics and ethical dilemmas. Education must target the translation of palliative care mandates into meaningful person-centered care for all persons liv-

ing with serious illness or chronic pain, including older persons, their families and health professionals who are situated in different health care settings. Funding for education and training is desperately needed to address deficits in knowledge about geriatric health and palliative systems of care, as well as applicable laws and regulations and their implications. Educational efforts will need to target the workforce gaps in geriatrics clinical training, encourage entry and retention in the aging field, and enhance positive perspectives of working with an aging population.

Policy Implementation and Systems-Level Change

Decisions made at the systems level, such as in the hospice model, relieve crisis and conflict at the bedside. Hospitals and nursing homes can begin to make systems decisions that are modeled on hospice care, such as integrating palliative care into standards of care, thus making palliative care accessible to all residents, and allocating appropriate resources to palliative care implementation. Changes at the systems level, including improved care coordination, communication and interdisciplinary team care planning and ethics committee review processes, will help to mitigate conflict-laden and emotionally stressful end-of-life choices for families and surrogates at the very time when they need to be investing their emotional resources in relational time and communication with their loved ones. Building “palliative environments” is also integral to the last phase of the strategy-policy implementation.¹⁰

Conclusion

A public health strategy holds great promise for strengthening equitable access to palliative systems of care that aim to relieve suffering and improve quality of life. The key components of that strategy—policy development, drug availability, education, and policy implementation—provide a blueprint for progressive change in the care of seriously ill persons. Pushing the boundaries of palliative care into the community and embedding the palliative approach in home and community-based services will be effective in helping to translate policy into meaningful interventions for frail and seriously ill people.

Endnotes

1. Temel JS, Greer JA, Muzikansky A, et al., *Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer*, New Eng. J. Med. (2010), 363(8):733-74, doi:10.1056/NEJMoa1000678.
2. Zimmermann C, Riechelmann R, Krzyzanowska M, et al., *Effectiveness of Specialized Palliative Care: A Systematic Review*, JAMA (2008), 299(14):1698-1709, doi:10.1001/jama.299.14.1698.
3. Bakitas M, Lyons KD, Hegel MT, et al., *Effects of a Palliative Care Intervention on Clinical Outcomes in Patients with Advanced Cancer*, JAMA (2009), 302(7):741-749, doi:10.1001/jama.2009.1198.
4. Greer JA, Traeger L, Bemis H, et al., *A Pilot Randomized Controlled Trial of Brief Cognitive-Behavioral Therapy for Anxiety in Patients with Terminal Cancer*, Oncologist (2012), 17(10):1337-1345, doi:10.1634/theoncologist.2012-0041.
5. Pirl WF, Greer JA, Traeger L, et al., *Depression and Survival in Metastatic Non-Small-Cell Lung Cancer: Effects of Early Palliative Care*, J. Clinical Oncology (2012), 30(12):1310-1315, doi:10.1200/JCO.2011.38.3166.
6. Seow H, Brazil K, Sussman J, et al., *Impact of Community Based, Specialist Palliative Care Teams on Hospitalisations and Emergency Department Visits Late in Life and Hospital Deaths: A Pooled Analysis*, BMJ 2014, 348:g3496, doi:10.1136/bmj.g3496.
7. Brumley R, Enguidanos S, Jamison P, et al., *Increased Satisfaction with Care and Lower Costs: Results of a Randomized Trial of In-Home Palliative Care*, J. Am. Geriatric Soc’y (2007), 55(7):993-1000, doi:10.1111/j.1532-5415.2007.01234.x.
8. Fernandes R, Braun KL, Ozawa J, et al., *Home-based Palliative Care Services for Underserved Populations*, J. Palliative Med. (2010), 13(4):413-419, doi:10.1089/jpm.2009.0216.
9. Palliative Care Patient Information Act, N.Y. Public Health Law § 2997-c(2) (PHL); Palliative Care Access Act, PHL § 2997-d.
10. Morrissey MB, Herr K, Levine C, *Public Health Imperative of the 21st Century: Innovations in Palliative Care Systems, Services, and Supports to Improve Health and Well-Being of Older Americans*, The Gerontologist (2015), 55(2):245-251, doi:10.1093/geront/gnu178.
11. Morrissey MB, Lang M, Newman B, *A Public Health Strategy to Living, Aging and Dying in Solidarity* (New York, NY & London, UK: Routledge Taylor & Francis Group 2019), doi: <https://doi.org/10.1201/b20617>.
12. Mann J, Gostin L, Bruskin S, et al., *Health and Human Rights*, Health Hum. Rights J. (1994), 1(1):6-23, <https://cdn2.sph.harvard.edu/wp-content/uploads/sites/125/2014/03/4-Mann.pdf>.
13. Olshansky SJ, Antonucci T, Berkman L, et al., *Differences in Life Expectancy Due to Race and Educational Differences Are Widening, and May Not Catch Up*, Health Affairs (2012), 31(8):1803-13, doi: 10.1377/hlthaff.2011.0746.
14. United Nations, Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: *The Right to the Highest Attainable Standard of Health* (Art. 12 of the Covenant), August 11, 2000, E/C.12/2000/4, <http://www.un.org/documents/ecosoc/docs/2001/e2001-22.pdf>.
15. Hunt P, Report of the Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Mental and Physical Health, United Nations, Economic and Social Council (ECOSOC), Jan. 17, 2007, A/HRC/4/28, <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G07/102/97/PDF/G0710297.pdf?OpenElement>.
16. *Id.* at p.2.
17. United Nations Office of the High Commissioner for Human Rights (OHCHR), Fact Sheet No. 31, *The Right to Health*, June 2008, <https://www.ohchr.org/Documents/Publications/Factsheet31.pdf>.
18. Gostin L, *Global Health Law* (Cambridge, MA: Harvard University Press 2014).
19. Connor SR, Sepulveda Bermedo MC (eds.), *Global Atlas of Palliative Care at the End of Life* (London/Geneva: Worldwide Palliative Care Alliance and World Health Organization, 2014), https://www.who.int/nmh/Global_Atlas_of_Palliative_Care.pdf.
20. *Id.* at p.9.
21. *Id.*
22. International Association for the Study of Pain (IASP), *Declaration of Montreal: Declaration that Access to Pain Management is a*

- Fundamental Human Right*, IASP 2010, <https://www.iasp-pain.org/DeclarationofMontreal>.
23. World Health Organization, *WHO Definition of Palliative Care*, 1990, <https://www.who.int/cancer/palliative/definition/en/>.
24. Stjernsward J, Foley KM, Ferris FD, *The Public Health Strategy for Palliative Care*, *J Pain Symptom Mgmt* (2007), 33:486-93, doi:10.1016/j.jpainsymman.2007.02.016.
25. WHA Resolution, WHA67.19—*Strengthening of Palliative Care as a Component of Comprehensive Care Throughout the Life Course*, Sixty-seventh World Health Assembly (2014), <http://apps.who.int/medicinedocs/documents/s21454en/s21454en.pdf>.
26. World Health Organization, *Planning and Implementing Palliative Care Services: A Guide for Programme Managers* (Geneva, Switzerland: WHO Press 2016), <http://www.who.int/iris/handle/10665/250584>.
27. *Id.* at p.45.
28. Knaul FM, Farmer PE, Krakauer EL, et al., *Alleviating the Access Abyss in Palliative Care and Pain Relief—an Imperative of Universal Health Coverage: The Lancet Commission Report*, *Lancet*, Advance online publication October 12, 2017, doi: [https://doi.org/10.1016/S0140-6736\(17\)32513-8](https://doi.org/10.1016/S0140-6736(17)32513-8).
29. Institute of Medicine (US) Committee on the Future Health Care Workforce for Older Americans, *Retooling for an Aging America: Building the Health Care Workforce* (Washington, DC: National Academies Press (US) 2008), doi: <https://doi.org/10.17226/12089>.
30. Voelker R, IOM: *Focus on Care for Aging Population*, *JAMA*, (2008), 299(22), 2611–2613, doi: 10.1001/jama.299.22.2611.
31. Alzheimer's Association, *2018 Alzheimer's Disease Facts and Figures*, <https://www.alz.org/media/HomeOffice/Facts%20and%20Figures/facts-and-figures.pdf>.
32. National Hospice and Palliative Care Organization, *Facts and Figures Hospice Care in America*, 2017 Edition (Revised April 2018), https://www.nhpco.org/sites/default/files/public/Statistics_Research/2017_Facts_Figures.pdf.
33. Dumanovsky T, Augustin R, Rogers M, et al., *The Growth of Palliative Care in U.S. Hospital: A Status Report*, *J. Palliat. Med.* (2016), 19(1):8-15, doi: 10.1089/jpm.2015.0351.
34. Smith AK, Thai JN, Bakitas MA, et al., *The Diverse Landscape of Palliative Care Clinics*, *J. Palliat. Med.* (2013), 16(6):661-8, doi: 10.1089/jpm.2012.0469.
35. Brumley R, Enguidanos S, Jamison P, et al., *Increased Satisfaction With Care And Lower Costs: Results Of A Randomized Trial Of In-Home Palliative Care*, *J. Am. Geriatric Soc'y*, (2007), 55(7):993-1000, doi: <https://doi.org/10.1111/j.1532-5415.2007.01234.x>.
36. Ng AYM, Wong FKY, *Effects of a Home-Based Palliative Heart Failure Program on Quality of Life, Symptom Burden, Satisfaction and Caregiver Burden: A Randomized Controlled Trial*, *J. Pain Symptom Mgmt.* (2018), 55(1):1-11, doi: <https://doi.org/10.1016/j.jpainsymman.2017.07.047>.
37. Gomes B, Calanzani N, Curiale V, et al., *Effectiveness and Cost-Effectiveness of Home-Based Palliative Care Services for Adults with Advanced Illness and Their Caregivers*, *Cochrane Database Sys. Rev's.* (2013), (6): 1-279, doi: 10.1002/14651858.CD007760.pub2.
38. Chen CY, Thorsteinsdottir B, Cha SS, et al., *Health Care Outcomes and Advance Care Planning in Older Adults Who Receive Home-Based Palliative Care: A Pilot Cohort Study*, *J. Palliat. Med.* (2015), 18(1):38-44, doi: 10.1089/jpm.2014.0150.
39. Centers for Medicare & Medicaid Services, *Medicare Care Choices Model*, <https://innovation.cms.gov/initiatives/medicare-care-choices/>, last accessed February 19, 2019.
40. Morley J, Paniagua M, Flaherty J, et al., *The challenges to the continued health of geriatrics in the United States*, *Annual Review of Gerontology and Geriatrics* (New York, NY: Springer Publishing Company 2008), 28(1): 27-44, doi: 10.1891/0198-8794.28.27.
41. United Nations, Department of Economic and Social Affairs, Population Division, *World Population Ageing 2015* (United Nations, New York, NY 2015), ST/ESA/SER.A/390, http://www.un.org/en/development/desa/population/publications/pdf/ageing/WPA2015_Report.pdf.
42. U.S. Department of Health and Human Services, *Multiple Chronic Conditions – A Strategic Framework: Optimum Health and Quality of Life for Individuals with Multiple Chronic Conditions* (Washington, DC: December 2010), https://www.hhs.gov/sites/default/files/ash/initiatives/mcc/mcc_framework.pdf.
43. Centers for Medicare & Medicaid Services, *Chronic Conditions Among Medicare Beneficiaries*, Chart Book 2012 (Baltimore, MD: October 2012), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/2012Chartbook.pdf>.
44. Jaul E, Barron J, *Age-Related Diseases and Clinical and Public Health Implications for the 85 Years Old and Over Population*, *Front Pub. Health* (2017); 5:335, doi: 10.3389/fpubh.2017.00335.
45. Rowe JW, Berkman L, Fried L, et al., *Preparing for Better Health and Health Care for an Aging Population: A Vital Direction for Health and Health Care*, Discussion paper, Vital Directions for Health and Health Care Series, National Academy of Medicine, Washington, D.C., <https://nam.edu/wp-content/uploads/2016/09/Preparing-for-Better-Health-and-Health-Care-for-an-Aging-Population.pdf>.
46. Reid MC, Ghesquiere A, Kenien C, et al., *Expanding Palliative Care's Reach in the Community Via the Elder Service Agency Network*, *Annals Palliat. Med.* (2017), 6(Suppl 1):S104-107, doi: 10.21037/apm.2017.03.10.
47. Parikh NS, Villanueva C, Kenien C, et al., *Results From a Community Needs Assessment: Addressing Palliative Care in Diverse Populations*, in 67th Annual Scientific Meeting "Making Connections: From Cells to Societies," *The Gerontologist* (2014), 54(Suppl 2):128, <https://doi.org/10.1093/geront/gnu106>.
48. Ghesquiere A, Gardner DS, McAfee C, et al., *Development of a Community-Based Palliative Care Screening Tool for Underserved Older Adults With Chronic Illness*, *Am. J. Hospice & Palliat. Care* (2018), 35(7):929-937, doi: <https://doi.org/10.1177/1049909117749467>.
49. Kozlov E, Cai A, Sirey JA, et al., *Identifying Palliative Care Needs Among Older Adults in Nonclinical Settings*, *Am. J. Hospice & Palliat. Care* (2018), 35(12):1477-82, doi: <https://doi.org/10.1177/1049909118777235>.
50. Gardner DS, Doherty M, Ghesquiere A, et al., *Palliative Care for Case Managers: Building Capacity to Extend Community-Based Palliative Care to Underserved Older Adults*, *Gerontology & Geriatrics Educ.* (2018), 15:1-16, doi: 10.1080/02701960.2018.1544129.
51. Radwany SM, Hazelett SE, Allen KR, et al., *Results of the Promoting Effective Advance Care Planning for Elders (PEACE) Randomized Pilot Study*, *Population Health Mgmt.* (2014), 17(2):106-111, doi: 10.1089/pop.2013.0017.
52. Koss SE, Weissman R Chow V, et al., *Training Community Clergy in Serious Illness: Balancing Faith and Medicine*, *J. Relig. Health* (2018), 57:1413, doi: <https://doi.org/10.1007/s10943-018-0645-8>.
53. Harvard University Initiative on Health, Religion, and Spirituality, *The National Clergy Project on End-of-Life Care*, <https://projects.iq.harvard.edu/rshm/national-clergy-survey-health-care-end-life>, last accessed February 19, 2019.
54. Lentz JC, *An Innovative Role for Faith Community Nursing: Palliative Care Ministry*, *J. Christian Nursing* (2018), 35(2):112-119, doi: 10.1097/CNJ.0000000000000478.

PUBLIC HEALTH LAW AND VULNERABLE POPULATIONS

55. Shalev A, Phongtankuel V, Kozlov E, et al., *Awareness and Misperceptions of Hospice and Palliative Care: A Population Based Survey Study*, *Am. J. Hospice & Palliat. Care* (2018), 35(3):431-439, doi: 10.1177/1049909117715215.
56. Seymour J, *The Impact of Public Health Awareness Campaigns on the Awareness and Quality of Palliative Care*, *J. Palliat. Med.* (2017), 20(S1):S30-36, doi: 10.1089/jpm.2017.0391.
57. Iowa Department of Public Health, Office of Health Care Transformation, *Palliative Care Awareness in Iowa*, a report from the Patient-Centered Health Advisory Council in response to House File 393 (December 2017), <https://idph.iowa.gov/Portals/1/userfiles/71/Palliative%20Care%20Awareness%20in%20Iowa.pdf>.
58. All Ireland Institute of Hospice and Palliative Care, *Public Awareness Campaign 2016*, Report on Public Awareness Raising, Palliative Care Week 2016 (December 6, 2016), <http://www.thepalliativehub.com/sites/default/files/Palliative%20Care%20Week%20Report%20%28Final%29%202016.pdf>.
59. Morrissey MB, Miller S, *American Public Health Association Policy Statement 2005-9 – Supporting Public Health's Role in Addressing Unmet Needs at the End of Life* (Washington, DC: American Public Health Association 2013).
60. Braun LT, Grady KL, Kutner JS, et al., and on behalf of the American Heart Association Advocacy Coordinating Committee, *Palliative Care and Cardiovascular Disease and Stroke: A Policy Statement From the American Heart Association and American Stroke Association*, *Circulation* (2016), 134(11): e198–e225, doi: <https://doi.org/10.1161/CIR.0000000000000438>.
61. American Psychological Association, *Resolution on Palliative Care and End-of-Life Issues*, adopted by APA Council of Representatives August 2017, Retrieved from: <http://www.apa.org/about/policy/palliative-care-eol.aspx>.
62. President's Commission on Combating Drug Addiction and the Opioid Crisis. (2017). Retrieved from https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
63. Institute of Medicine, *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research* (Washington, D.C.: National Academies Press 2011), doi: <https://doi.org/10.17226/13172>.
64. U.S. Department of Health and Human Services, *National Pain Strategy: A comprehensive population level strategy for pain* (Washington, DC: March 18, 2016), https://iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf.
65. The Interagency Pain Research Coordinating Committee, *Federal Pain Research Strategy*, NIH Office of Pain Policy (2017), https://iprcc.nih.gov/sites/default/files/iprcc/FPRS_Research_Recommendations_Final_508C.pdf.

Thank you for being a NYSBA and Health Law Section member!



Renew your memberships for 2019 by visiting www.nysba.org/renew or calling the Member Resource Center at 800-582-2452.

Have you considered also joining the Elder Law and Special Needs Section at only \$30 per year? Network with knowledgeable lawyers in your field and continually learn important issues most pressing in your area of practice. Let us know when you renew!

Don't let your NYSBA membership lapse, enroll in Automatic Renewal.



**NEW YORK STATE
BAR ASSOCIATION**

Supervised Injection Facilities: A Collision Between Public Health Policy and State and Federal Law

By Joyce Tichy and Jerry Lynch

In 2017 there were 70,237 drug overdose deaths in the United States, up from 63,632 the year before, which resulted in an age-adjusted rate of overdose deaths that was 9.6 percent higher in 2017 than in 2016.¹ The total number of United States drug overdose deaths since 1999 now exceeds 660,000, with increases in every one of those years. The increasing overdose death rate contributed to an overall decline in United States life expectancy in 2016 and 2017, reversing for the first time the upward life expectancy trend that the United States had enjoyed during the prior 100-year period beginning at the end of World War I. Disturbing as it is, this data is no longer shocking to those who read the news, which indicates the pervasiveness and intractability of the opioid epidemic. Although initial figures for 2018 suggest that the opioid overdose death rate may have peaked, this long-developing crisis shows little sign of abating or of responding to any quick solutions in spite of the countless headlines.

Society and its policy makers are now using criminal, civil and regulatory tools to pursue an expanding list of potentially guilty parties that includes pharmaceutical companies, drug cartels, and even oversight agencies such as the Food and Drug Administration, and the Drug Enforcement Agency, and drug users themselves. Numerous congressional hearings, lawsuits and criminal investigations have ensued. For those who work in public health, however, questions about who is responsible are secondary to how this massive public health tragedy can be addressed. With opioid use disorder now afflicting an estimated 2.1 million people,² and invariably consuming their families, employers, communities and almost all the social and medical service providers tasked with the ensuing need for their care, the issue for public health policy makers is how to help those affected with chronic use disorders survive and remain functionally integrated in society.

The U.S. Department of Health and Human Services has published a *5-Point Strategy to Combat the Opioid Crisis*, with the five points being better addiction prevention, treatment and recovery services, better data, better pain management, better targeting of overdose reversing drugs and better research.³ A strategy that is not found on this list, or in any federally funded initiative or federally approved health program, however, involves supervised injection facility (SIF) programs. SIFs, which are also called safe injection sites and harm reduction sites, have been in place in various countries throughout the world for more than 30 years, which generally reported favorable to excellent outcomes in reducing overdose-related deaths.

Although their configuration varies, the general setup for such a facility is to arrange a sanitary setting where users are permitted to bring their drugs and inject them. The facility is not involved in obtaining or administering the prohibited drug, but maintains trained professionals on standby to reverse overdoses or other medical emergencies, and often encourages drug users to pursue counseling and other social services.

As far back as 2008, scholars laid out the potential legal arguments in favor of SIFs. Beleskey *et al.*⁴ presented an analysis that year which mapped out a legal path but conceded that it was a “rocky” one given the various legal, social and political hurdles present in the United States. Burris *et al.* followed in 2009, providing a robust case supporting the proposition that SIFs, like syringe exchanges and medical marijuana programs, can be implemented under state and local laws within the nation’s federalist scheme, which reserves both the police power and the power to regulate health to state and local authority under the Tenth Amendment to the U.S. Constitution.⁵ Earlier this year, Gostin *et al.* again outlined various legal avenues available to entities interested in opening such sites, concluding that “[c]riminal law has no value in public health initiatives like SIFs designed to prevent harms and counsel clients.”⁶

Yet legal uncertainty remains. In 2018 U.S. Department of Justice Deputy Attorney General Rod Rosenstein volunteered his perspective that such a program would be ill-considered and counter-productive, and issued a warning that those involved would be “vulnerable to civil and criminal enforcement” under federal drug laws. Still, despite this disapproving message, numerous cities throughout the United States, including Seattle, Philadelphia, San Francisco, and Portland, Maine, are seriously considering SIFs in light of the favorable scientific evidence⁷ and the otherwise bleak options they face for addressing the opioid overdose problem. Philadelphia, which is experiencing what has been called a “staggering” overdose death toll where one neighborhood has been labeled “the largest open-air market for heroin on the East Coast,”⁸ is seriously testing the concept by encouraging a nonprofit named Safehouse to open a facility.⁹ In response to the Department of Justice’s threats, former Pennsylvania Governor Ed Rendell, who is an incorporator of the

JOYCE TICHY is a health law attorney who practices in New York, New Jersey and Connecticut. JERRY LYNCH works in private practice and teaches Legal Aspects of Healthcare at New York University.

nonprofit, declared that he remains steadfastly in favor of this initiative, stating, “They can come and arrest me first.”¹⁰ In a countermove, the United States Attorney for the Eastern District of Pennsylvania filed a declaratory judgment action against Safehouse in February 2019 seeking to bar the facility from opening. The complaint asserts that “[I]t does not matter that Safehouse claims good intentions in fighting the opioid epidemic. What matters is that Congress has already determined that Safehouse’s conduct is prohibited by federal law without any relevant exception.”¹¹

As this escalating dispute demonstrates, the concept of an SIF represents one of two divergent philosophies about how to address the intractable problem of opioid drug addiction. The federal approach, as demonstrated by the Justice Department’s interpretation and application of federal law, continues to be a “war on drugs,” which treats the consumption of illegal drugs as a deviant activity to be addressed from a criminal justice perspective, whereas local governments are, by their actions and words, rejecting that approach as both outdated and a demonstrable failure given the facts on the ground. Faced with the unabated and pervasive problem at hand, these localities are moving away from the criminal enforcement approach and instead toward a medical treatment model that addresses addiction as a chronic life-threatening medical condition, with SIFs considered one viable feature in the continuum of care for a highly challenged at-risk population.

New York City, for its part, has taken steps that demonstrate it favors Philadelphia’s approach as a public health matter. New York City Health completed a study in 2017 entitled *Overdose Prevention in New York City: Supervised Injection as a Strategy to Reduce Opioid Overdose and Public Injection*,¹² that lays out the public health case for SIFs. While also advocating other kinds of public health initiatives to combat the crisis, it summarizes the current state of scientific studies and literature favoring SIFs and concludes that “[s]upervised injection is an evidence-based health intervention for people who inject drugs.”¹³ Anticipating the potential legal challenges that face such a program, however, the study also includes an analysis by Columbia Law School Professor Kristen Underhill that outlines the various laws that could be invoked to shut down an SIF and impose legal liability on the participants, including drug users, staff members and property owners. To address these issues, the legal analysis proposes a number of strategies, as outlined below, for SIFs in New York City, which echo the approaches outlined by other scholars but with particular attention to New York law. As the following summary of that analysis makes clear, while there are various routes that can be taken in New York City to implement SIFs, each legal barrier that currently exists at the federal and state level is best considered and addressed strategically and in depth in light of the likelihood of legal challenges to SIFs.

Legal Challenges

The federal Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, poses the first significant challenge to SIFs. Under § 844, anyone in possession of a controlled substance could face fines and/or imprisonment, which would place patients and providers at risk.¹⁴ New York State’s criminal possession code, N.Y. Penal Law § 220.03, similarly punishes persons possessing controlled substances or paraphernalia, although it differs from the CSA by specifically permitting syringe-exchange programs, whereby it allows for possession of trace amounts of substances in used and ostensibly exchanged syringes. Equally important is New York’s law criminalizing injecting “a narcotic drug” into another under N.Y. Penal Law § 220.46. On the other hand, New York has also enacted a “Good Samaritan” law, N.Y. Penal Law § 220.78, which promotes the use of emergency services for persons experiencing drug overdose, exempting the victim and the respondent from penalty.¹⁵ Thus, although the settings sought by SIFs do not in themselves present as an emergency, when the emergency occurs in an SIF, the Good Samaritan law may apply, rendering an effective means for personnel to avoid criminal penalty.

SIF staff and facility owners face unique challenges of their own. Section 856 of the CSA, the so-called “Crack House Statute,” imposes penalties to anyone owning or operating a space “for the purpose of...using any controlled substance.” Penalties include fines up to \$500,000 for individuals and up to \$2,000,000 for institutions, and may include imprisonment for both staff and facility owners.¹⁶ Staff may also face possession charges for handling the narcotics under CSA §§ 841(a)(1) and 844. Furthermore, Section 881 allows the federal government to seize property used for purposes enumerated in § 856.

Staff could also face civil liability for administering the narcotics, even if they are not actually injecting the patients themselves. The “Good Samaritan” law would not apply to medical providers, and the providers would be subject to the same medical malpractice standards as other professionals in their jurisdiction. While there is no publicized record of anyone dying at an SIF, should a patient expire at the site, providers may be sued by the decedent’s estate for wrongful death.¹⁷ Dram shop laws such as N.Y. General Obligations Law §§ 11-101 and 11-103 may also apply if patients are allowed to leave the site while intoxicated or under the influence.¹⁸ While unlikely to prevail, these civil causes of action serve as a reminder that until both criminal and civil codes are revised in order to legally establish SIFs without repercussion to patients and staff, they stand to be legally at risk for participating in such programs despite the potential public benefits.

Another consideration for practitioners is how their participation in an SIF will be viewed under their profes-

sional codes of ethics, which might affect not only their community standing but also licensure and malpractice liability. Section 29.19(b)(1) of the New York Board of Regents Rules on Unprofessional Conduct, which is applicable to health practitioners, includes in the definition of unprofessional conduct “willful or grossly negligent failure to comply with substantial provisions of Federal, State or local laws, rules or regulations governing the practice of the profession.” However, a number of recent analyses support the conclusion that providing post-injection medical assistance within an SIF is consistent with medical ethical standards in that the assistance is a separate moral act from the illegal drug use in the SIF and is designed to reduce harm without encouraging the drug use itself. The Massachusetts Medical Society published a report in 2017 concluding that “SIFs are in keeping with the MMS Code of Ethics whereby physicians are obligated to provide

Prevailing Law—U.S. or New York?

There is also debate as to whether the Supremacy Clause of the Constitution would allow federal law to preempt state law on these matters. Arguments in favor of states’ rights to allow SIFs originate from language in the CSA, namely that the drafters did not intend for the statute to apply to states seeking to engage in bona fide health programs aimed at reducing potential harm caused by controlled substances.²³ States are also given discretion on how to regulate medical practice, which SIFs would clearly fall under. (“If SIFs are considered part of medical practice, or if supervising injections is viewed as within a provider’s existing authority, SIFs may succeed in a courtroom challenge under § 856.”)²⁴ Yet while states are given authority over regulating medicine and ensuring the safety of their citizens, federal law may still prevail under the Supremacy Clause.

“Despite the effectiveness of NEPs at reducing transmission, public support for NEPs remain low. Of 1,004 participants in a study published by Emma McGinty on legalizing safe consumption sites, ‘only 29 percent supported legalizing safe consumption sites in their communities and only 39 percent supported legalizing syringe services programs...’”

compassionate and respectful medical care to all people while respecting individual human dignity and rights,”¹⁹ and noting that the same conclusion had been reached by medical societies in Canada and Australia. The American Medical Association agreed with the Massachusetts Medical Society’s findings, endorsing SIFs.²⁰ An ethics analysis by Fleshner and Greenacre²¹ likewise concluded that assistance to individuals in an SIF would meet ethical standards under a utilitarian consequentialist analysis in that the practice would maximize benefit to the greatest number of people by reducing overall mortality for drug users, as well as under a deontological theory provided that the universe of individuals affected is defined to be drug users rather than society at large. And Bayley *et al.* concluded that assistance to an SIF by religious institutions such as Catholic hospitals would meet the ethical standards of the Catholic Church,²² although cautioning that care should be taken to ensure that the institution is not complicit in the drug use itself. Medical aid in an SIF may thus fall into the category of acts that can be classified as ethical even while the legal controversy persists, and the professional conduct standards could be considered to be upheld by the distinctions outlined in the ethics analyses that distinguish such aid from the encouragement of drug use.

Avenues to Establish SIFs

Legally establishing SIFs in New York would likely originate with state legislative action. The New York State legislature has the power to statutorily authorize SIFs under the Tenth Amendment to the United States Constitution, which reserves health, safety, and wellness regulations to states.²⁵ In 2017, Linda Rosenthal, a Manhattan Representative in the New York State Assembly, introduced such a bill, A.8534, and Gustavo Rivera, a Bronx member of the New York State Senate, introduced a companion Senate version, S.8809. If passed, these bills would remove state criminal and civil concerns, deter arrest, and provide additional defenses against prosecution by federal authorities.

In the alternative to legislation, the State Executive can establish SIFs through executive power. The Department of Health can promulgate rules or use existing powers to allow for SIFs.²⁶ See PHL § 201: “promote or provide diagnostic and therapeutic services for... communicable diseases, medical rehabilitation...and other conditions and diseases affecting public health.” The commissioner of the State Department of Health can also authorize possession of syringes. The governor can declare a state of disaster for “natural or man-made causes” and direct state agencies to respond under. N.Y. Exec. Law §§ 20-29.

New York City executives have the same powers, although in the absence of agreement by the state a city ordinance would be vulnerable to challenge by state prosecutors, and SIF staff may still face disciplinary charges. Under New York City Charter § 556, the New York Department of Health and Mental Hygiene can regulate the health needs of city residents, operate public health centers and provide services for “the ambulant sick and needy persons of the city” (N.Y.C.C. § 556).²⁷

Lastly, the city could establish an SIF as a research study under PHL § 201.²⁸ The researchers would need to obtain Institutional Review Board (IRB) approval with clients as participants. A research license could be obtained to research controlled substances under PHL § 3324. The State Department of Health could issue the license for two years, with sites to be managed by the Department of Health Bureau of Narcotic Enforcement under PHL § 201(d). Researchers could then obtain a federal license to be exempt from the CSA under 21 U.S.C. § 822(b). The U.S. Attorney General’s Office reviews federal licenses for research studies and considers the following factors: (1) recommendation by the state licensing board, (2) the researchers’ experience in research with controlled substances, (3) researchers’ conviction records under federal and state controlled substances laws, (4) compliance with “applicable state, federal, or local laws,” and five threats to public health and safety.²⁹ Implementing SIFs as a research study has several advantages, especially that SIF staff and patients would be safe from prosecution.³⁰ The two-year period would also allow SIFs to gain public support so that appropriate state legislative proposals could be introduced to reform or keep SIFs after the two-year research study period has transpired.

While applying for a two-year research study has potential for positive outcomes, there is no guarantee that after two years the public will back having an SIF in their community. To the contrary, establishing an SIF as a research study could prompt greater debate than pursuing the legislative route. Stalling the legislature’s opportunity to decide the issue of SIFs by using 21 U.S.C. § 822(b) could result in considerable backlash from opponents, whereas lobbying for comprehensive legislation on the matter would allow the electorate to conduct their own research without a two-year delay. Furthermore, while establishing an SIF through 21 U.S.C. § 822(b) may result in an operational clinic sooner than lobbying efforts, the two years research study would conclude with a new election cycle. At present, both the legislative and executive branches are progressive, providing a ripe opportunity to enact SIF legislation, nixing the need for the research study stall altogether.

In sum, although there is uncertainty in how the federal government would respond to establishing SIFs

in New York, there are viable avenues the state legislative and executive branches can take. Alternatively, SIFs can begin as a two-year research study, thereby avoiding legal conflict while also providing time to gather support to maintain SIFs after the two-year period expires. Regardless of which avenue is taken, establishing SIFs in New York would enhance public safety and address a public health crisis that has thus far lacked the attention it deserves.

For those in favor of setting up an SIF, it is likely that progress will turn on the ability to navigate successfully between two very different norms, one reflected in current laws on the books that suggest the best way to curtail the use of illegal drugs or assistance to those who do so is by criminalizing it, and the other arising out of scientific evidence favoring experimentation with promising interventions. Given the unlikelihood of a change in law at the federal level, it is instructive to review the history of needle exchange programs (NEPs) in the United States, for which a very similar dichotomy has been in play for many years.

Many states have enacted legislation that allows for NEPs, with New York ranking in the top five for the total number of programs available in the state. New York has 23 NEPs, California has 43, and 11 states have none at all.³¹ In 2019, NEPs play a vital role in ensuring that the spread of diseases transmittable by blood does not become an epidemic.³² In 2015, Indiana declared a state of emergency for an HIV outbreak that resulted in establishing an NEP. “There were 181 HIV infections diagnosed between Nov. 18, 2014, and Nov. 1, 2015, in Scott County, making it the largest HIV outbreak in a nonurban area in the U.S. among people who inject drugs.”³³ Reports after the establishment of the NEP showed “an 88 percent reduction in syringe sharing, a 79 percent reduction in syringe sharing to divide drugs and an 81 percent reduction in sharing of other injection equipment.”³⁴

Despite the effectiveness of NEPs at reducing transmission, public support for NEPs remains low.³⁵ Of 1,004 participants in a study published by Emma McGinty on legalizing safe consumption sites, “only 29 percent supported legalizing safe consumption sites in their communities and only 39 percent supported legalizing syringe services programs...”³⁶ Additional findings from the survey conducted by Dr. McGinty, an assistant professor in the Department of Health Policy and Management at Johns Hopkins University, showed that attitudes mainly differed based on political party affiliation, with little difference attributed to age, race, or gender.³⁷ Public perception would thus need to undergo significant change before NEPs become a reality nationwide. On the other hand, the leadership role that New York has taken in establishing

NEPs, like its many past public health initiatives, may be a bellwether for similar leadership in establishing SIFs.

As these public health initiatives move forward, a key consideration will be the need to address the pervasive social stigma that adheres to drug addiction programs based on concerns for crime, litter and negative impacts on surrounding communities, along with moral disapproval of addicted individuals and a concern that society should not be seen as encouraging illegal drug use. These perceptions are increasingly being addressed by scientific studies indicating that on the whole crime does not appear to increase from the existence of these programs, along with other studies that demonstrate that adherence to simple solutions such as non-medication assisted abstinence and detoxification programs have high repeated failure rates. Studies show that relapse rates for people with substance use disorders is 40-60 percent;³⁸ thus, drug users may undergo repeated relapses before successfully moving to a sustained drug-free status. Considering that the most hazardous period for a drug user is the post-detoxification relapse period, when drug resistance is lowest and the likelihood for overdose is highest, an SIF that enhances the possibility of survival while also providing options for recovery appears to provide a more reliable pathway to recovery than the current retributive approach. In order for policy and law to align with the evidence, however, the most significant factor may be the need to identify and address the assumptions underlying the punitive approach to drug addiction by means of communication and education. Under a modernized approach, SIFs would be included as one of the treatment and recovery services authorized by public policies like the United States Department of Health's *5 Point Strategy*, and thus become part of a larger toolbox of ongoing treatment and prevention methods to address the crisis as it exists today. Over the long term, success in addressing the opioid crisis would ultimately be demonstrated by the reduced need for SIFs altogether.

Endnotes

- Hedegaard H, Miniño AM, Warner M. Drug overdose deaths in the United States, 1999–2017. NCHS Data Brief, no 329. Hyattsville, MD: National Center for Health Statistics. 2018, posted at United States Center for Disease Control, Drug Overdose Deaths in the United States, 1999–2007, <https://www.cdc.gov/nchs/products/databriefs/db329.htm>, accessed December 6, 2018.
- U.S. Department of Health and Human Services, "What is the Opioid Epidemic?" <https://www.hhs.gov/opioids/about-the-epidemic/index.html>, accessed December 6, 2018; Center for Behavioral Health Statistics and Quality (CBHSQ). 2015 National Survey on Drug Use and Health: Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2016.
- U.S. Department of Health and Human Services, *5-Point Strategy to Combat the Opioid Crisis*, <https://www.hhs.gov/opioids/about-the-epidemic/hhs-response/index.html>, accessed December 6, 2018.
- Beletsky, Leo et al. *The Law (and Politics) of Safe Injection Facilities in the United States*, Am J. Public Health: 2008 February , 98(2): 231-237, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2376869/>, accessed December 7, 2018.
- Burris, Scott C. and Anderson, Evan D. and Beletsky, Leo and Davis, Corey S., *Federalism, Policy Learning, and Local Innovation in Public Health: The Case of the Supervised Injection Facility*, St. Louis University Law Journal, Vol. 53, 2009, July 6, 2009, available at SSRN: <https://ssrn.com/abstract=1430567>.
- Gostin LO, and Hodge JG, and Gulinson CL. *Supervised Injection Facilities: Legal and Policy Reforms*, JAMA, published online February 07, 2019. doi:10.1001/jama.2019.0095.
- Dolan, Kate et al. *Drug consumption facilities in Europe and the establishment of supervised injecting centres in Australia*, Harm Reduction Digest 10, Drug and Alcohol Review (2000) 19, 337-46 <https://doi.org/10.1080/713659379>, accessed December 7, 2018.
- New York Times Magazine, *Trapped by the Walmart of Heroin*, October 6, 2018, <https://www.nytimes.com/2018/10/10/magazine/kensington-heroin-opioid-philadelphia.html>, accessed December 6, 2018.
- Whelan, Aubrey, *Here's how Safehouse, Philly's proposed safe-injection site, will operate*, The Inquirer, <http://www2.philly.com/philly/health/addiction/safe-injection-site-philadelphia-safehouse-faq-20181008.html>—Safehouse informational web site, <https://www.safehousephilly.org/about/faqs>, accessed December 7, 2018.
- WHYY, *Former Gov. Ed Rendell says 'Arrest Me First' for backing supervised injection facility [updated]*, <https://whyy.org/articles/former-gov-ed-rendell-says-arrest-me-first-for-backing-safe-injection-facility/> (accessed December 6, 2018); Allyn, Bobby, *'Come and Arrest Me': Former Pa. Governor Defies Justice Department on Safe Injection*, WHYY (October 10, 2018), accessed December 6, 2018.
- United States of America v. Safehouse, a Pennsylvania nonprofit, and Jeanette Bowles, as Executive Director*, Case No. 2:19-cv-00519-GAM (E.D. Pa., complaint filed February 5, 2019).
- NYC Health, *Overdose Prevention in New York City: Supervised Injection As A Strategy to Reduce Opioid Overdose and Public Injection* (October 3, 2017), <https://www1.nyc.gov/assets/doh/downloads/pdf/public/supervised-injection-report.pdf>, accessed December 6, 2018.
- Id.* at 4.
- Id.* at 130, 21 U.S.C. § 844.
- NYC Health Report at 132.
- Id.* at 132.
- Id.* at 137.
- Id.* at 138.
- Fitzgerald, *Establishment of a Pilot Medically Supervised Injection Facility in Massachusetts*, Report of the Task Force on Opioid Therapy and Physician Communication (April 2017), <https://www.massmed.org/advocacy/state-advocacy/sif-report-2017/>, accessed March 9, 2019.
- American Medical Society, *AMA wants new approaches to combat synthetic and injectable drugs*, Press Release (June 12, 2017), <https://www.ama-assn.org/press-center/press-releases/ama-wants-new-approaches-combat-synthetic-and-injectable-drugs>, accessed March 10, 2019.
- Fleshner and Greenacre, *Evaluation of supervised injection facilities as an ethically sound approach to treatment of injection drug abuse*, University of Western Ontario Medical Journal, Vol. 82 No. 2 (2017), <https://ojs.lib.uwo.ca/index.php/uwomj/article/view/2051>, accessed March 9, 2019.
- Bayley, Bouchard and Yant, *Assessing the Ethical Issues in 'Safe Injection' Sites*, Health Care Ethics USA (Fall 2017), <https://www.>

chausa.org/docs/default-source/hceusa/assessing-the-ethical-issues-in-safe-injection-sites.pdf?sfvrsn=0, accessed March 9, 2019.

23. *Id.* at 134, Burris at 36.

24. *Id.* at 134.

25. NYC Health Report at 134, Burris at 18.

26. *Id.* at 142-43.

27. *Id.* at 144.

28. *Id.* at 145-46.

29. 21 U.S.C. § 821.

30. *Id.* at 146.

31. amfAR Opioid & Health Indicators Database, http://opioid.amfar.org/indicator/num_SSps.

32. Indiana University, Medical Xpress, <https://medicalxpress.com/news/2018-06-syringe-exchange-key-role-hiv.html>.

33. *Id.*

34. *Id.*

35. McGinty, Emma et al., Johns Hopkins University Bloomberg School of Public Health, <https://www.jhsph.edu/news/news-releases/2018/public-support-for-needle-exchange-programs-safe-injection-sites-remains-low-in-US.html> (June 5, 2018).

36. *Id.*

37. *Id.*

38. National Institute on Drug Abuse, Drugs, Brains, and Behavior: The Science of Addiction, <https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/treatment-recovery>, accessed February 13, 2019.

NEW YORK STATE BAR ASSOCIATION

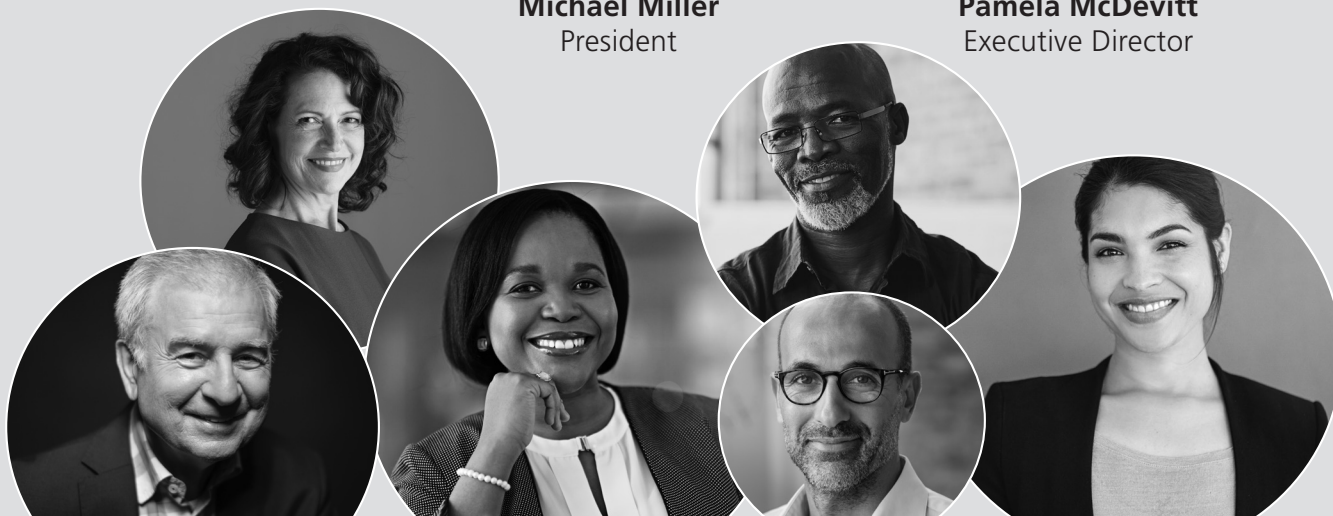
Thank you!

For your **dedication**, for your **commitment**,
and for recognizing the **value** and **relevance**
of your membership.

As a New York State Bar Association member, your support helps make us the largest voluntary state bar association in the country and gives us credibility to speak as a unified voice on important issues that impact the profession.

Michael Miller
President

Pamela McDevitt
Executive Director



NIFLA and the Future of Health Warnings

By Thomas Merrill

Pregnancy centers are facilities operated by anti-choice groups that counsel women and families to forgo abortions and instead choose life for their unborn children. Some offer limited medical services like sonograms and pregnancy testing. Others, while appearing to be medical clinics, do not offer any medical services and simply provide anti-abortion counseling to pregnant women who wittingly or unwittingly come to them. Concerned that unsuspecting women might be going to these centers, and thus might not be getting timely reproductive services, some states and localities have tried to require that pregnancy centers disclose their agendas. In 2011, for example, New York City passed a local law that required such centers to disclose (1) whether any licensed medical professionals were on staff supervising the services being offered at the center; (2) that the city encourages pregnant women to consult with a licensed provider; and (3) whether they provide, or provide referrals for, abortion, emergency contraception, and prenatal care.¹ Finding the city to have a compelling interest in preventing delays in women accessing reproductive services, the Second Circuit in *Evergreen Association, Inc. v. City of New York* upheld the first required disclosure but struck down the second two because they were not narrowly tailored to that interest.²

California also attempted to impose disclosure requirements on pregnancy centers. In June, the United States Supreme Court ruled in *National Institute of Family and Life Advocates v. Becerra* (NIFLA)³ that its disclosure requirements, which differed for licensed and unlicensed centers, likely violated the First Amendment. Significantly, Justice Thomas in his majority opinion treated the required disclosures as “content-based” speech restrictions that presumptively were unconstitutional; his decision ignored prior decisions that traditionally have employed different standards of review in commercial speech cases, prompting some to warn that the status of other disclosure laws protecting health is now uncertain.⁴

Commercial Speech Prior to NIFLA

Commercial speech was not constitutionally protected until 1976, when the Supreme Court decided *Virginia State Pharmacy Board v. Virginia Citizens Consumer Council*.⁵ Thirty-four years earlier, the Court upheld a New York City regulation that prohibited businesses from distributing commercial handbills expressly holding that advertising was not protected by the First Amendment.⁶ *Virginia State Pharmacy Board* overturned that decision. Noting that the First Amendment protects not only speakers, but also the right of consumers to hear and receive information, the Court held that commercial speech is “not wholly outside

the protection” of the First Amendment and ruled that Virginia could not prohibit pharmacists from advertising the prices of the prescription drugs they were selling.

Four years later, in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*,⁷ the Supreme Court adopted an intermediate level of scrutiny for assessing the constitutionality of regulations restricting commercial speech. That case involved a challenge to a policy of the New York Public Service Commission that prohibited electric utilities from promoting the use of electricity. Originating during the fuel shortages of the 1970s, the policy was intended to promote conservation. Finding commercial speech to be less protected by the Constitution than other forms of expression, the Court employed a four-part analysis in its review of the advertising prohibition. First, it determined that the affected communication was indeed entitled to First Amendment protection because it concerned lawful activity and was not misleading. Next, it determined that New York had a substantial interest in promoting fuel conservation. It then assessed both whether the policy directly advanced that interest, and whether it was not more extensive than necessary in doing so. Finding that while New York’s advertising ban was directly related to its interest in promoting conservation, the Court nonetheless found the prohibition to violate the First Amendment because the ban on speech was broader than it needed to be.

In *Zauderer v. Ohio*,⁸ an even lower standard of review emerged for reviewing laws that compel commercial disclosures. A personal injury attorney printed an advertisement in several newspapers directed at women who had been injured after using the Dalkon Shield, a type of intrauterine contraceptive device that generated numerous product liability suits in the 1980s. Contrary to Ohio’s disciplinary rules for attorneys, the advertisements did not inform the attorney’s potential clients that, while his fees were contingent upon a recovery, they would still be liable for costs if they sued the maker of the Dalkon Shield and lost. The Supreme Court of Ohio found that Zauderer had violated this and other rules governing advertisements by attorneys and recommended that he be publicly reprimanded. He appealed to the Supreme Court, challenging Ohio’s right to discipline him because of the content of his advertisements. Because disclosures enhance the information available to consumers, the Supreme Court distinguished disclosure requirements from prohibitions

THOMAS MERRILL is the General Counsel to the New York City Department of Health and Mental Hygiene.

on speech. Provided that a requirement to disclose factual and uncontroversial information is neither unjustified nor unduly burdensome, the First Amendment only requires that it be reasonably related to the state's interest in wanting the information disclosed. Ohio, thus, could require that attorneys advise potential contingency fee clients that they might be liable for the costs of an unsuccessful litigation in order to prevent consumer deception.

While Ohio's interest in *Zauderer* was preventing consumer deception, other disclosures of factual information subsequently have been upheld advancing different state interests using the same standard of reasonableness. In *New York State Restaurant Association v. New York City Board of Health*,⁹ the Second Circuit applied the *Zauderer* test when finding that New York City could mandate that chain restaurants post calorie information on their menus and menu boards. It rejected the restaurant industry's argument that the rational basis test should only apply where necessary to prevent consumer deception, and instead held the standard should be applied whenever the government was requiring that truthful and uncontroversial information be disclosed in a commercial transaction.¹⁰ Reviewing a federal country-of-origin labeling requirement for meat products, the D.C. Circuit in *American Meat Institute v. U.S. Dept. of Agriculture* similarly found that the information being disclosed was both factual and reasonably related to the government's interests in both promoting health and the sale of American products.¹¹

Thus, prior to *NIFLA*, the constitutionality of a warning mandate was likely to be determined applying either the *Zauderer* or *Central Hudson* test. If the warning statement was factual and noncontroversial, it needed to only be rationally related to a government end to survive. Otherwise, intermediate scrutiny would be applied.

NIFLA

The California legislature enacted the California Reproductive Freedom, Accountability, Comprehensive Act (FACT) to regulate pregnancy centers. Its purpose was to ensure that California residents be fully informed about their rights and available services when making reproductive health care decisions. FACT required a center to comply with one of two different sets of disclosure requirements depending on whether the center had any type of license from the State of California to operate. For those that were licensed to be a primary care, specialty or intermittent clinic, FACT required that they post a notice in their waiting rooms advising potential clients that California provides women with free and low-cost services, including abortion. Certain clinics, however, like those operated by a federal agency or participating in certain state programs, were excluded from these disclosure requirements. If a center had no license to operate, it was

required to post a notice, both in its waiting room and at its entrance, disclosing that it was unlicensed and that the services it was offering were not supervised by a medical professional. The disclosure also had to appear on an unlicensed facility's advertising materials. The content of the notices for both licensed and unlicensed centers were crafted by California, and each had to be posted conspicuously meeting specific font and language requirements.

The law was challenged by a licensed center, an unlicensed center and *NIFLA*—an association of pregnancy crisis centers. Petitioners claimed that the law's disclosure requirements compelled speech in violation of the First Amendment. After their motion for a preliminary injunction was denied in the district court, petitioners appealed to the Ninth Circuit Court of Appeals. Finding the disclosure requirements for licensed facilities to be regulations of professional speech subject to intermediate scrutiny, the Circuit concluded that they were narrowly drawn and advanced California's interest in alerting women to the availability of state-funded family planning services. As to the disclosure requirements for unlicensed facilities, it held that they could survive even strict scrutiny (without finding that it should apply) because California's interest in "presenting accurate information about the licensing status of individual clinics is particularly compelling."¹²

After granting certiorari, the Supreme Court reversed the Ninth Circuit and enjoined California from enforcing the disclosure requirements. Writing for the majority, Justice Thomas found the requirement to be a "content-based" regulation of speech and, thus, "presumptively unconstitutional" with California bearing the burden of demonstrating that it was narrowly tailored to serve compelling state interests.

Although some Courts of Appeal, including the Ninth Circuit, had recognized "professional speech" as a category of speech subject to only intermediate scrutiny, the Supreme Court has not. Observing that the Court was "reluctant to mark off new categories of speech for diminished constitutional protection,"¹³ the majority found that California had failed to identify a sufficient reason for treating professional speech differently from any other kind of speech. While *Zauderer* allows for a lower level of scrutiny when professionals must disclose factual and uncontroversial information, the majority concluded that it did not apply because the notices did not relate to the services provided by the centers and instead were about abortion. Intimating that the disclosure requirements should be strictly construed because they regulated the content of speech, and without referencing *Central Hudson*, the majority applied intermediate scrutiny because it found that the rule could not survive even that level of review. Assuming California's interest was educating low-income women, the notice requirements were

“wildly under-inclusive” and suspiciously seemed to target centers with a particular viewpoint. California also failed to show why a public information campaign would not work. While it claimed that it had attempted one, and eligible women still were not enrolling in its state-funded services, the state did not show a sufficient nexus between the failed campaign and the under-enrollment to justify making the pregnancy centers be its messenger.

For the non-licensed centers, California based FACT on its concern that pregnant women were going to the centers believing that they were clinics that provided medical services including abortion. Finding that the disclosure requirements could not survive even under *Zauderer*, the majority applied its rational review test. California failed to demonstrate a justification for the disclosure that was anything but hypothetical. Moreover, the notice requirements were unduly burdensome, requiring “a curiously narrow subset of speakers” to bear a government conscripted message on signs at their doors and in their waiting rooms, and on any advertisement they might place for their services.

Throughout his opinion, Justice Thomas several times criticized California for imposing notice requirements on centers with a particular view on abortion. Four judges in the majority joined a separate concurrence authored by Justice Kennedy to further “underscore that the apparent viewpoint discrimination [in FACT] is a matter of serious constitutional concern.”¹⁴ Nevertheless, the concurrence agreed with Judge Thomas that the case should not be decided on that ground because, even if applied more broadly, the disclosure requirements were likely unconstitutional.

Justice Breyer wrote a blistering dissent that Justices Ginsburg, Sotomayor and Kagan joined. It warned that the majority’s decision invited future litigations challenging other health and safety warnings, which now were at risk because “every disclosure law could be considered ‘content based,’ for virtually every disclosure law requires individuals to speak a particular message.”¹⁵ Responding to this concern, the majority tried to limit the reach of its decision, stating that it did “not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products.”¹⁶ But, the dissent noted that the disclosures at hand were related to health and countered that the majority had invited “courts around the Nation to apply an unpredictable First Amendment to ordinary and economic regulation, striking down disclosure laws that judges may disfavor, while upholding others, all without grounding their decisions in reasoned principle.”¹⁷

The dissenters would have applied the *Zauderer* test. They would have affirmed the Ninth Circuit because

they believed the disclosure requirements were rationally related to California’s interest in ensuring that pregnant women know when they are getting care from licensed professionals. While the topic of abortion might be special, the dissent noted that *NIFLA* is hard to reconcile with *Planned Parenthood of Southeast Pennsylvania v. Casey*,¹⁸ where the Supreme Court upheld a Pennsylvania law that required medical providers performing abortions to provide information to their patients about adoption services. The dissent accused the majority of being less than evenhanded in its distinction of *Casey* and of interpreting the First Amendment in a way that resulted in it applying unfairly depending on the point of view of the affected speaker.

The Status of Health Warnings After *NIFLA*

At best, *NIFLA* is a decision limited to speech about abortion and health officials can take Justice Thomas at his word when he writes that the legitimacy of other warnings remains unchanged. If, however, the case truly was only about abortion, it would have been better decided on grounds of viewpoint discrimination. But that would have required the majority either to overrule *Casey* or to struggle even more explaining why pro-life birthing centers cannot be compelled to give notice of state-funded abortion services while pro-choice physicians can be compelled to tell patients seeking abortions about adoption as an alternative to their choice. At worst, Justice Breyer’s ominous warning will prove true—all health and safety warnings will be subject to challenge by those who do not like their messages, and the viability of each will depend on whether the judge reviewing the requirement is favorably, or unfavorably, predisposed toward it.

Since *44 Liquormart, Inc. v. Rhode Island*,¹⁹ Justice Thomas has been advocating that commercial speech be treated no differently than other speech. There, the Supreme Court struck down a law that prohibited liquor stores from advertising the retail prices of alcoholic beverages. A majority of the Court’s justices found that the prohibition failed to pass the *Central Hudson* test because it was neither narrowly drawn nor did it materially advance Rhode Island’s interest in promoting temperance. In a separate concurring opinion, Justice Thomas argued that the *Central Hudson* test should be abandoned and that all restrictions of speech should be strictly construed. While *NIFLA* does not expressly abandon *Central Hudson*, it moves closer to this result by holding that warnings are content-based regulations of speech that presumptively are unconstitutional.

While the *Zauderer* standard affords a lower level of scrutiny in some cases, there is less certainty about the types of disclosure requirements to which it will be applied. The Court in *NIFLA* purposely did not decide

what type of government interest is sufficient to trigger rational review, leaving that question open for future cases to decide. Governments, however, bear the burden of showing a legitimate interest in having information disclosed and should be prepared to support that interest with evidence at the risk of it be dismissed as “purely hypothetical” like California’s.²⁰ Even if justified by a legitimate state interest, a disclosure about any topic on which professionals might in good faith disagree may now be too controversial to merit review under *Zauderer*. In addition to abortion, the Court cited physician gag laws,²¹ physician-assisted suicide and medical marihuana as examples of other areas where the government’s policing of speech might potentially be problematic. And, even if in furtherance of a legitimate government end and not about a controversial topic, a regulation might still violate the First Amendment if it unduly burdens those required to disclose factual information.

NIFLA has already impacted three pending health warning cases. In 2016, the FDA published a final rule imposing new warning requirements for cigars and other tobacco products. A federal court initially upheld the warnings,²² but following *NIFLA* the petitioner moved before the same district judge to enjoin enforcement of the warning requirement pending its appeal of that ruling to the Court of Appeals. Finding that “serious legal questions” existed about the application of the *Zauderer* standard, she granted the injunction.²³ In 2015, San Francisco passed a law requiring a statement on any outdoor advertisement for a sugary beverage warning that added sugars contribute to obesity, diabetes and tooth decay. After a panel on the Ninth Circuit initially found the requirement to be unconstitutional,²⁴ an *en banc* review was ordered.²⁵ That argument was delayed pending the Supreme Court’s decision in *NIFLA*, and did not happen until September 25, 2018. The 11-judge panel devoted much of its questioning on the accuracy of the warning statement, whether the rule was under-inclusive because it applied only to advertisements for sugary beverages, and the burden its size requirements posed on advertisers.²⁶ On January 31, 2019, the Ninth Circuit enjoined San Francisco from enforcing its law, finding that that American Beverage Association was likely to prevail on its claim that the law was unconstitutional.²⁷ Also in 2015, the City of Berkeley passed an ordinance requiring cell phone retailers to disclose to customers that using cell phones can lead to exposure to radio-frequency radiation exceeding federal guidelines. Although the Ninth Circuit found the warning requirement to be constitutional,²⁸ the Supreme Court granted a writ of certiorari. After deciding *NIFLA*, it remanded the case to the Ninth Circuit for further consideration in light of that decision.²⁹

In his dissent, Justice Breyer warns that regulations requiring physicians to discuss treatment options with

patients diagnosed with breast cancer or child passenger restraint systems with parents of newborn children being discharged from the hospital are now at risk of being found to violate the Constitution. Whether that is true or not, states and localities can expect more First Amendment challenges to regulations that require warnings, with the ultimate reach of *NIFLA* being decided in future litigations.

Endnotes

1. New York City Administrative Code § 20-816.
2. 740 F.3d 233 (2d Cir. 2014).
3. 585 US __, 138 S. Ct. 2361 (2018).
4. See, e.g., *The Supreme Court’s Crisis Pregnancy Case – Implications for Health Law*, Parmet, et al., NEJM 8/29/18.
5. 425 U.S. 748 (1976).
6. *Valentine v. Chrestensen*, 316 U.S. 52 (1942).
7. 447 U.S. 557 (1980).
8. 471 U.S. 626 (1985).
9. 556 F.3d 114, 121-122 (2d Cir. 2009).
10. See also *National Elect. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001), applying *Zauderer* when upholding a Vermont law that required manufacturers to label products containing mercury.
11. 760 F.3d 18 (D.C. Cir. 2014).
12. *Nat. Inst. of Family and Life Advocates v. Harris*, 839 F.3d 823, 843 (9th Cir. 2016).
13. 138 S.Ct. at 2371.
14. 138 S.Ct. at 2378.
15. *Id.* at 2381 (quoting his own concurrence in *Reed v. Town of Gilbert*, 576 U.S. __, 135 S.Ct. 2218, 2234-35 (2015), which listed numerous regulations that involve content discrimination).
16. *Id.* at 2376.
17. *Id.* at 2381.
18. 505 U.S. 833 (1992).
19. 517 U.S. 484 (1996).
20. 138 S.Ct., at 2377.
21. *Id.* at 2374, citing the concurrence in *Wollschlaeger v. Florida*, 84 F.3d 1293, 1328 (11th Cir. 2017) which emphasized that the First Amendment did not allow Florida to prohibit physicians from discussing gun ownership with their patients.
22. *Cigar Association of America v. FDA*, 315 F. Supp. 3d 143, 165 (D.D.C. 2018).
23. *Cigar Association of America v. FDA*, 317 F. Supp. 3d 555 (D.D.C. 2018).
24. *American Beverage Ass’n v. San Francisco*, 871 F.3d 884 (9th Cir. 2017).
25. *American Beverage Ass’n v. San Francisco*, 880 F.3d 1019 (9th Cir. 2018).
26. <https://www.courthousenews.com/en-banc-9th-circuit-grills-san-francisco-on-soda-warning-label-law/>.
27. *American Beverage Ass’n v. San Francisco*, __ F.3d __, 2019 Westlaw 387114 (9th Cir. 2019).
28. *CTIA v. City of Berkeley*, 854 F.3d 1105 (9th Cir. 2017).
29. *CTIA v. City of Berkeley*, __ U.S. __, 138 S.Ct. 2708 (2018).

NEWS *flash*

What's Happening in the Section

New Litigation Committee—A Message from the Chair

Dear Members:

I am very excited to announce the creation and formal kickoff of the NYSBA Health Law Section Health Care Litigation Committee. Many attorneys in our Section are active in litigating health law-related matters in the various civil, criminal, and administrative venues that exist for resolving health care-related matters, and each of you are invited and encouraged to join!

The Health Care Litigation Committee will explore the unique and challenging issues related to litigating disputed matters within our rapidly changing health care industry.

The Committee hopes to provide our health law litigators with an opportunity for in-depth exploration of a variety of issues, including venue, remedies, and procedures that are relevant to handling litigation and other controverted health care disputes common to our Section.

Our kickoff meeting was on Wednesday, January 16, 2019, 7:45 a.m.-8:45 a.m., at the New York Hilton Midtown, 1335 Avenue of the Americas, NYC, during the NYSBA Annual Meeting. This was immediately prior to the Health Law Section's Annual Meeting CLE program. The meeting included a planning discussion for the coming year.

We hope you will consider joining the Committee.

Linda Jane Clark, Esq.
Barclay Damon LLP, Albany
Chair, Health Care Litigation Committee

Committee's Mission Statement

The Committee's Mission Statement is below. Joining the Committee is complimentary for NYSBA Health Law Section members.

To join the Committee, email Amy Jasiewicz at: ajasiewicz@nysba.org.

Mission Statement:

In recognition of the quickly growing and ever-evolving field of health care litigation, the Health Law Litigation Committee will focus on areas of health law involving the adversarial litigation process, both civil and criminal, that are relevant to health care disputes.

This Committee seeks to study and review challenges unique or relevant to participants in the health care industry, including patients, providers, and payors, as well as promote collegial sharing among NYSBA lawyers, and the dissemination of information and expertise in both litigation and other resolutions of health care-related disputes.



ACCESS FOUR SECTION CLE PROGRAMS ONLINE

- Legal Issues Surrounding Eye, Organ and Tissue Donation
- Disrupting the System: Innovation and Collaboration in Health Care in New York
- E-Health Clinical Records and Data Exchange Parts I & II (only Part II offers credit)
- Health Law Section Fall 2017 Meeting

Visit www.nysba.org/HLS for more information



Section Committees and Chairs*

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

Continuing Legal Education

Sandra C. Maliszewski
67 Florence Avenue
Oyster Bay, NY 11771
maliszewskis@acpny.com

E-Health and Information Systems

Daniel Meier
Benesch Friedlander Coplan & Aronoff
Continental Plaza II
411 Hackensack Avenue, 3rd Flr.
Hackensack, NJ 07601-6323
dmeier@beneschlaw.com

Nathan Garrett Prystowsky
Janet H. Prystowsky, M.D., PC
110 East 55th Street, 7th Floor
New York, NY 10022-4554
ngp@janetprystowskymd.com

Ethical Issues in the Provision of Health Care

Brendan Sidney Parent
NYU School of Professional Studies
7 East 12th Street, Suite 825b
New York, NY 10003
brendan.parent@nyu.edu

Health Care Litigation

Linda Jane Clark
Barclay Damon LLP
80 State Street
Albany, NY 12207-2207
lclark@barclaydamon.com

Health Care Providers and In House Counsel

Carolyn B. Levine
Memorial Sloan Kettering
1275 York Ave., 20th Floor
New York, NY 10065-6094
levinec@mskcc.org

Margaret J. Davino
Fox Rothschild LLP
101 Park Avenue
New York, NY 10271-1699
mdavino@foxrothschild.com

Anoush Koroghlian Scott
Jackson Lewis, PC
677 Broadway, 9th Floor
Albany, NY 12207
Anoush.scott@jacksonlewis.com

Health Professionals

Jay B. Silverman
Ruskin Moscou & Faltischek PC
1425 RXR Plaza
East Tower, 15th Floor
Uniondale, NY 11556-1425
jsilverman@rmfpc.com

Legislative Issues

James W. Lytle
Manatt, Phelps & Phillips, LLP
30 S. Pearl Street
Albany, NY 12207
jlytle@manatt.com

Long-Term Care

Jane Bello Burke
Hodgson Russ LLP
677 Broadway, Suite 301
Albany, NY 12207
jbburke@hodgsonruss.com

Medical Research and Biotechnology

Alex C. Brownstein
BioScience Communications
250 Hudson Street, 9th Floor
New York, NY 10013
alex.brownstein@bioscicom.net

Samuel J. Servello
205 East 10th Street, #5D
New York, NY 10003
samservello.barmail@gmail.com

Membership

Lisa D. Hayes
Assistant General Counsel
The Brookdale Hospital Medical Ctr.
321 Katz, 1 Brookdale Plaza
Brooklyn, NY 11212-3198
lhayes@bhmcny.org

Nominating

Salvatore J. Russo
573 West 4th Street
Brooklyn, NY 11204
sjr747881@aol.com

Professional Discipline

Joseph L. DeMarzo
41 Hathaway Lane
White Plains, NY 10605-3609
jdemarzo@optonline.net

Douglas M. Nadjari
Ruskin Moscou Faltischek, PC
1425 Rxr Plaza
Uniondale, NY 11556
dnadjari@rmfpc.com

Public Health

Veda Marie Collmer
WebPT, Inc.
625 S. 5th Street
Phoenix, AZ 85004
vedacollmer@yahoo.com

State Constitutional Convention—Focus on Health

Hermes Fernandez
Bond, Schoeneck & King, PLLC
22 Corporate Woods, Suite 501
Albany, NY 12211
hfernandez@bsk.com

Young Lawyers

Nicole R. Ozminkowski
Harris Beach P LLC
99 Garnsey Road
Pittsford, NY 14534
nozminkowski@harrisbeach.com

Cassandra Rivais
Rivkin Radler LLP
9 Thurlow Terrace
Albany, NY 12203
Cassandra.Rivais@rivkin.com

* To update your information, contact
NYSBA's Member Resource Center at
1-800-582-2452.

Publication and Editorial Policy

Persons interested in writing for this *Journal* are welcomed and encouraged to submit their articles for consideration. Your ideas and comments about the *Journal* are appreciated as are letters to the editor.

Publication Policy:

All articles should be submitted to:

Brendan Parent, J.D.
Phone: 212-998-7065
Email: brendan.parent@nyu.edu

Submitted articles must include a cover letter giving permission for publication in this *Journal*. We will assume your submission is for the exclusive use of this *Journal* unless you advise to the contrary in your letter. Authors will be notified only if articles are rejected. Authors are encouraged to include a brief biography with their submissions.

Editorial Policy: The articles in this *Journal* represent the authors' viewpoints and research and not that of the *Journal* Editorial Staff or Section Officers. The accuracy of the sources used and the cases cited in submissions is the responsibility of the author.

Subscriptions

This *Journal* is a benefit of membership in the Health Law Section of the New York State Bar Association.

The *Journal* is available by subscription to non-attorneys, libraries and organizations. The subscription rate for 2019 is \$185.00. Send your request and check to Newsletter Dept., New York State Bar Association, One Elk Street, Albany, NY 12207.

Accommodations for Persons with Disabilities:

NYSBA welcomes participation by individuals with disabilities. NYSBA is committed to complying with all applicable laws that prohibit discrimination against individuals on the basis of disability in the full and equal enjoyment of its goods, services, programs, activities, facilities, privileges, advantages, or accommodations. To request auxiliary aids or services or if you have any questions regarding accessibility, please contact the Bar Center at 518-463-3200.

Copyright 2019 by the New York State Bar Association.
ISSN 1530-3926 ISSN 1933-8406 (online)

HEALTH LAW JOURNAL

Editor

Brendan Parent
NYU School of Professional Studies
7 East 12th Street, Suite 825b
New York, NY 10003
brendan.parent@nyu.edu

Section Officers

Chair

Robert A. Hussar
Barclay Damon
60 State Street
Albany, NY 12207
RHussar@barclaydamon.com

Chair-Elect

Hermes Fernandez
Bond, Schoeneck & King, PLLC
22 Corporate Woods, Suite 501
Albany, NY
hfernandez@bsk.com

Vice-Chair

Karen L.I. Gallinari
15 Wilcox Avenue
Yonkers, NY 10705
karen.gallinari@nychhc.org

Secretary

Nathan Garrett Prystowsky
110 East 55th Street, 7th Floor
New York, NY 10022-4554
ngp@janetprystowsky.com

Treasurer

Anoush Koroghlian Scott
Jackson Lewis, PC
677 Broadway, 9th Floor
Albany, NY 12207
Anoush.scott@jacksonlewis.com



NEW YORK STATE BAR ASSOCIATION

HEALTH LAW SECTION

One Elk Street, Albany, New York 12207-1002

NON PROFIT ORG.
U.S. POSTAGE
PAID
ALBANY, N.Y.
PERMIT NO. 155

*You Are Invited to
Join the Legacy Society of
The New York Bar Foundation*



Legacy donors provide a better tomorrow for generations of New Yorkers in need.

Your gifts help the Foundation fund charitable and educational law-related projects in perpetuity – safeguarding access to justice and the rule of law in New York State.

A Legacy Gift is the greatest honor that a donor can bestow upon the Foundation.

Please join these guardians of justice by making a bequest or establishing a planned gift to the Foundation of \$1,000 or more.

Call the Foundation at **518/487-5650** for more information
or download the form at **www.tnybf.org/legacysociety**.



**THE NEW YORK
BAR FOUNDATION**

Advancing Justice and Fostering the Rule of Law