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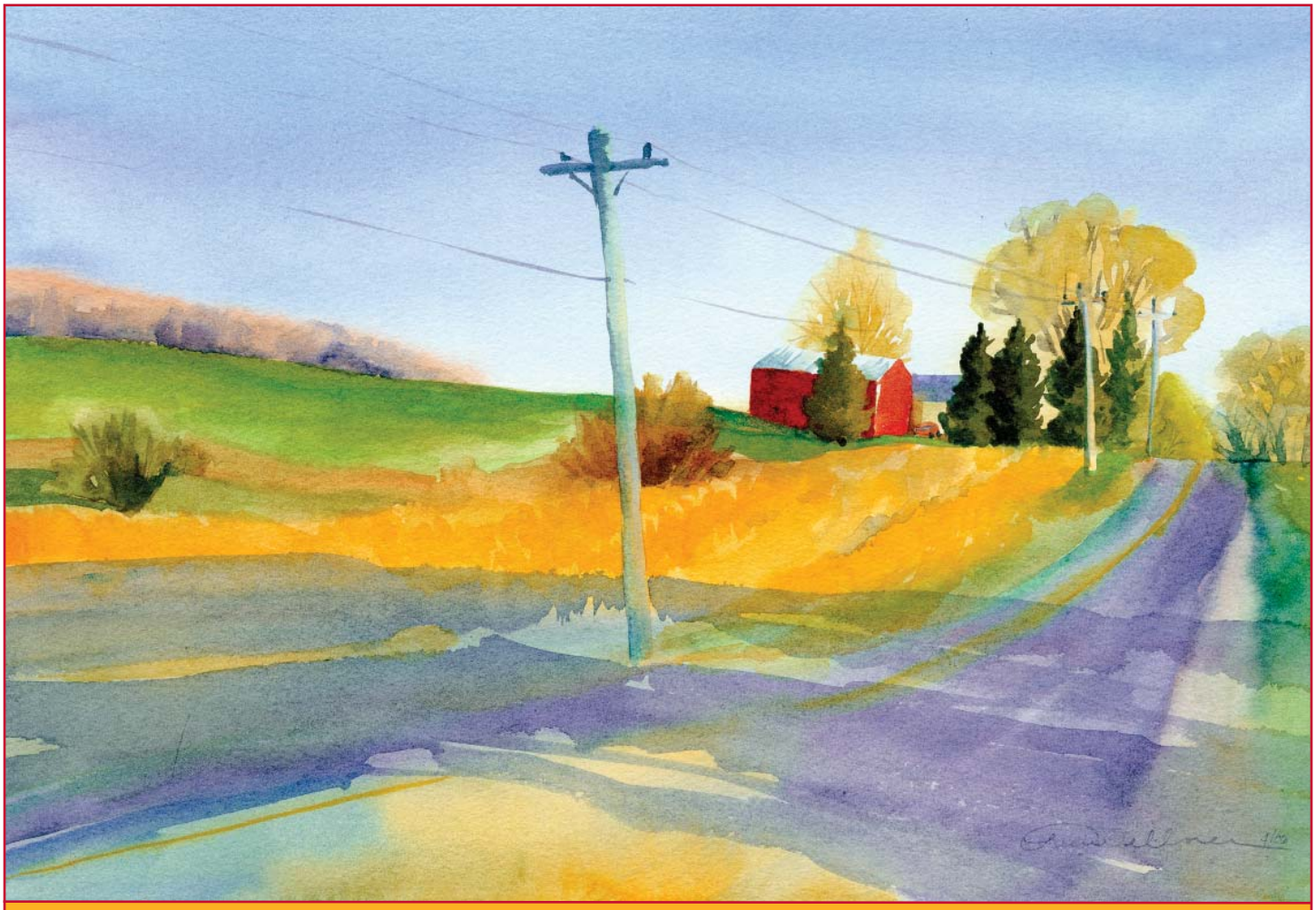

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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A Message from the Section Chair

Welcome to the Health Law Section

This past year-and-a-half has had a large number of significant legislative and regulatory initiatives imposed on providers. As a result New York health lawyers face a more-than-usual challenge in trying to learn and advise clients about changes in law. Participating in the Health Law Section—attending conferences, joining committees, reading the *Journal*—can be more helpful than ever.

Here is a brief summary of some key recent legislative initiatives. This edition of the *Journal* also includes articles that address two of these laws—the Nonprofit Revitalization Act and medical marijuana law, in greater depth. Also, Jim Lytle's regular column, *In the New York State Legislature*, provides an invaluable review of the session.

Limits on Billing by Out-of-Network Providers

The 2014 New York State budget made changes to the New York Insurance Law, Public Health Law and Financial Services Law intended to protect patients, especially those receiving emergency services, from "surprise bills" from out-of-network providers. These changes, which will not be effective until at least 2015, place a number of duties on hospitals, health care professionals, group practices, diagnostic and treatment centers and health centers (on behalf of professionals), including:

- They must disclose in writing or through the web the plans in which they participate and affiliated hospitals .
- If a professional or health center does not participate in a patient's plan, before receiving non-emergency services, the patient must be informed that the charge (or an estimate) is available on request. Additionally, upon request by the patient, the actual amount or estimate (or schedule of fees if a health center) to be billed absent unforeseen medical circumstances must be disclosed.

If a physician "arranges" anesthesia, lab, pathology, radiology, or the care of an assistant at surgery for a patient scheduled to receive hospital services, the physician is required to provide the name, address and phone number of that other physician, as well as how to determine the plans in which the other doctor participates.

Hospitals must post on hospital websites: standard charges, participating health plans, a statement that physician services provided in the hospital are not part of hospital charges, a statement that physicians in the hospital may not participate in same plans, and contact information for contracted physician groups, including anesthesia, radiology and pathology. The hospital must advise patients (i) to check with their physician as to other physicians involved, (ii) whether anesthesia, pathology or radiology services are anticipated, (iii) how to timely determine the health plans of physicians providing services at the hospital, and (iv) that a dispute resolution process exists between out-of-network providers and insurers if there is a dispute as to the bill.

A dispute resolution process will be established to resolve disputes between out-of-network providers and insurers in an effort to protect patients from surprise bills. "Independent dispute resolution entities" will be comprised of licensed physicians in the same or similar specialties as the applicable provider. Under the new dispute resolution process, the provider, the health plan or an uninsured patient may submit a dispute regarding fees to the independent dispute resolution entity.

The independent dispute resolution entity will choose between the fee charged by the provider versus the fee proposed by the health plan, based on which it determines to be more "reasonable." If settlement is possible or if both fees are "unreasonably extreme," negotiation will be encouraged. If a patient involved in a dispute is uninsured, then the entity may determine a reasonable fee. The entity's determination will be binding on all of the parties. The losing party must bear the costs of the dispute process. If a settlement is reached, the parties will share the costs.

Regulations to implement the law are still be developed by the State.

I-STOP (the Internet System for Tracking Over-Prescribing/Prescription Monitoring Program)

In an effort to control prescription drug overdoses, effective August 27, 2013, most prescribers in New York are required to consult the Prescription Monitoring Program (PMP) Registry when writing prescriptions for Schedule II, III, and IV controlled substances. (This does not apply to administering a controlled substance.) The PMP Registry provides practitioners with direct, secure access to view dispensed controlled substance prescription histories for their patients 24 hours a day/7 days a week. Physicians must first have an active "Health Commerce Account" with the State of New York, which may be established through the Department of Health's Health Commerce System at https://hcsteamwork1.health.state.ny.us/pub/top.html. Patient reports will include all con-

trolled substances that were dispensed in New York State and reported by the pharmacy/dispenser for the past six months. The intent is to provide information to allow practitioners to better evaluate their patients' treatment with controlled substances and determine whether there may be abuse or non-medical use.

Practitioners may authorize designee(s) to check the registry on their behalf. In addition, pharmacists, who did not previously have access to the registry, have access to the registry to review the controlled substance history of an individual for whom a prescription for controlled substances is presented.

There are exceptions to the duty to consult the registry, e.g., (A) it is not reasonably possible to access the registry in a timely manner; (B) no other practitioner or designee who is authorized to access the registry is reasonably available; and (C) the quantity of the controlled substance prescribed does not exceed a 5 day supply.

All physicians should ensure that they have a health commerce account and regularly check the Registry when writing prescriptions for Schedule II, III and IV controlled substances, and hospitals and other physician employers should have policies and procedures in place to require such.

Changes to the New York Not-for-Profit Corporation Law: Nonprofit Revitalization Act

Editor's note: This edition of the Journal *carries a more comprehensive summary of the Nonprofit Revitalization Act, starting on page 39.*

New York's Not-for-Profit Corporation Law ("NPCL") was substantially updated by the Nonprofit Revitalization Act of 2013 ("Act"), effective July 1, 2014. The changes in the law require that not-for-profit corporations in New York review their bylaws to determine whether revisions are appropriate or required, as well as review certain policies.

There are a number of provisions that may require changes to a not-for-profit corporation's bylaws, including:

1. **Mandatory whistleblower policy.** Every not-for-profit corporation with 20 or more employees and annual revenue exceeding $1,000,000 must adopt a whistleblower policy that requires (i) procedures for the reporting of violations or suspected violations of laws or corporate policies including procedures for preserving the confidentiality of reported information; (ii) that someone in the corporation be designated to administer the whistleblower policy and to report to the applicable committee or Board; and (iii) that a copy of the policy be distributed to all directors, officers, employees and volunteers who provide substantial services to the corporation.

2. **Related party transactions.** NFP corporations may not enter into a related party transaction unless the Board has determined the transaction to be fair, reasonable and in the corporation's best interest. "Related party" is defined under the Act to include officers, directors, "key employees," their relatives and certain entities in which they have a specified ownership interest. Key employee is a new concept, defined as any person who is in a position to exercise substantial influence over the affairs of a corporation, as referenced under the Code's excess benefit transaction provisions.

   Prior to entering into a transaction in which a related party has a substantial financial interest, the Board (or an authorized committee) must (i) consider alternative transactions, (ii) approve the transaction by not less than a majority vote of the Board or committee members present at the meeting; and (iii) document the basis for the Board or authorized committee's approval, including its consideration of any alternative transactions. A related party cannot participate in deliberations or voting related to related party transactions. However, the Board or authorized committee may request that a related party present information concerning the proposed transaction prior to the deliberations or voting.

3. **No employee as Chair.** Effective July 1, 2016, to ensure an independent Board, no employee may serve as chair of the Board, or hold any other title with similar responsibilities.

4. **Audit oversight required by Board**. For corporations that solicit charitable contributions and have gross receipts exceeding $500,000, either the Board or an audit committee of independent directors must (i) oversee the accounting and financial reporting processes of the organization and the audit of its financial statements; (ii) annually retain an independent auditor; (iii) review with the independent auditor the results of the audit (including the management letter); and (iv) oversee the adoption, implementation of and compliance with any conflict of interest policy or whistleblower policy (unless otherwise performed by another committee consisting solely of independent directors).

   Charities with annual revenue exceeding $1 million have additional responsibilities. The independent directors or audit committee must (i) review with the independent auditors the scope and planning of the audit prior to commencement of the audit; (ii) upon completion of the audit, discuss

with the independent auditor material risks and weaknesses in internal controls identified, restrictions on the scope of the auditor's activities or access to requested information, any significant disagreement between the auditor and management, and the adequacy of the corporation's accounting and financial reporting processes; and (iii) annually consider the performance and independence of the independent auditor.

"Independent director" is defined as a director who (i) has not been an employee or does not have a relative who was a key employee of the not-for-profit or an affiliate of the not-for-profit in the past three years; (ii) has not received or who does not have a relative who has received $10,000 or more in direct compensation from the not-for-profit or an affiliate in the past three years other than reasonable director's fees; and (iii) is not a current employee of, or does not have a substantial financial interest in, any entity that has made payments to or received payments from the not-for-profit or an affiliate of the not-for profit for property or services in an amount that exceeds the lesser of $25,000 or 2 percent of the entity's consolidated gross income in the past three years.

5. **Notices and communications**. Facsimile or email of certain consents, notices, waivers, proxies and financial statements, both for members and for trustees, is now allowed. In addition, directors may participate in Board or committee meetings through video screen communications as well as conference call, as long as all members can hear each other at the same time.

6. **Number of Board members**. Not-for-profit corporations without members no longer are required to fix the number of directors in their bylaws. Instead, the number may be fixed by action of the Board pursuant to a specific provision of the by-laws, or may be any number within a range set forth in the by-laws. (Therefore, not-for-profit corporations without members may now change the number of directors without amending their by-laws.)

7. **Approval of real estate transactions**. Whereas the NPCL previously required approval by a two-thirds vote of the Board for a purchase, sale, mortgage or lease of real property, such can now be approved by a majority vote of the Board or a majority vote of a Committee. However, if the transaction involves all or substantially all of the assets of the corporation, a two-thirds vote of the entire Board is still required unless the Board has 21 or more members, in which event a majority vote of the Board is sufficient.

8. **Committees.** The Act eliminates the distinction between standing and special committees. Instead, it distinguishes between committees of the Board (which may have only directors as members and have the authority to bind the corporation) and committees of the corporation (which may include non-directors but do not have the authority to bind the corporation). Additionally, any committee authorized by the Board to purchase or dispose of real estate must report promptly to the Board, and in no event after the next scheduled meeting of the Board.

9. **Privacy of board addresses**. Not-for-profits must produce a list of directors and officers if requested by a member of the not-for profit or a law enforcement agency, but the Act eliminates the requirement to disclose the home address of officers and directors.

In addition to potential bylaws changes, there are requirements under the Act that may require changes to an organization's policies. All not-for-profit corporations must have a conflict of interest policy containing specific provisions, including a requirement that the existence and resolution of the conflict be documented in the corporation's records, including in the minutes of any meeting at which the conflict was discussed or voted upon. In addition, organizations that are registered or required to be registered to solicit contributions in New York must file audit reports with the Attorney General, depending upon the amount of annual gross revenue.

The Act made it easier to incorporate a new not-for-profit corporation. Previously, all not-for-profit corporations established in New York had to be characterized as one of four types—Type A, B, C and D. Now, not-for-profit corporations will be classified as either "charitable" or "non-charitable." Additionally, the requirement to obtain prior consent of the State Education Department has been changed to apply only to not-for-profit entities operating schools, libraries, museums or historical societies. (Other not-for-profit organizations providing education will be required to provide a certified copy of the certificate of incorporation to the Commissioner of Education after filing with the Secretary of State.)

Lastly, the Act also makes it easier to obtain certain approvals that previously required a court proceeding, namely, approvals of "assets" dissolutions; the change, elimination or addition of a purpose or power of a charitable corporation; and the sale, lease, exchange or other disposition of all or substantially all of a corporation's assets. Such may now be approved by the Attorney General.

Limits on Executive Compensation

Pursuant to Executive Order 38, thirteen New York State agencies, including the Department of Health,

promulgated regulations that prohibit covered providers from using state funds or state-authorized payments to pay more than $199,000 per year in executive compensation to a "covered executive"(a director, trustee, officer or key employee whose salary is incurred in connection with management and overhead and can't be attributed to provision of program services). These regulations went into effect on July 1, 2013, and apply as of the first day of the covered entity's next reporting period. Since many health care entities have a calendar year fiscal period, if they are covered, the limit applied as of January 1, 2014.

Providers are covered if they:

- have a contract or other agreement with the Department of Health or another governmental entity to provide services and receive state funds or state-authorized payments;
- receive at least $500,000 during the covered reporting period and prior year; and
- state funds or state-authorized payments (including Medicaid and Medicaid managed care payments) constitute at least 30% of their total annual in-state revenues in those years.

Executive compensation includes all forms of payments or benefits to a covered executive, including salary, bonuses, dividends, and other financial arrangements reportable on a W-2 or 1099, such as cars and housing. It can also include employer contributions to retirement and deferred compensation plans that are not consistent with those provided to other employees.

If a provider has funding in addition to state funds, it may pay an executive more than $199,000, provided (1) the executive's total compensation is below the top quartile in his or her field, according to a compensation survey; and (2) the executive's compensation has been approved by the provider's Board of Directors after a review of the comparability data. Compensation commitments under existing agreements in place prior to July 1, 2012 are "grandfathered" during the term of the agreement (excluding renewals), but such agreements may not extend beyond April 1, 2015.

Providers are required to file an "EO#38 Disclosure Form" with the state 180 calendar days following the conclusion of the provider's covered reporting period. A covered provider with a calendar year reporting period (i.e., calendar year 2014) would have to file the EO#38 Disclosure within 180 days after December 31, 2014. If the covered provider has more than ten key employees, the covered provider must report only the ten key employees with the highest level of executive compensation during the reporting period. In some cases, covered executives of related organizations must be included.

These regulations have been challenged, and on April 9, 2014, in *Agencies for Children's Therapy Services, Inc. v. New York Department of Health*, the Nassau County Supreme Court held that the Department of Health ("DOH") unconstitutionally exceeded proper regulatory authority in promulgating the regulations. The court found that both the Governor and DOH exceeded their respective authority, particularly in light of the fact that the NYS Legislature previously rejected the proposed budgetary legislation that included an identical proposal to cap executive compensation and administrative expenses through provisions virtually identical to the terms of the Executive Order.

However, a July 10, 2013 decision by the Suffolk County Supreme Court in *Concerned Home Care Providers, Inc. v. New York State Department of Health et al.*, 969 N.Y.S.2d 743 (2013) upheld the regulations. The State has appealed the Nassau County court decision.

Smoking Prohibition Outside Hospitals

New York State's smoking law (New York Public Health Law Section 1399-o) as of October 29, 2013 prohibits smoking anywhere on the grounds of a general hospital or residential health care facility. It also prohibits smoking in areas within 15 feet of any building entrance or exit, and within 15 feet of any entrance to or exit from the grounds of a general hospital or residential health care facility. There is a narrow exception for patients of residential health care facilities and their visitors or guests, but the exception does not extend to employees, or to patients of general hospitals and their visitors or guests.

The smoking law's restrictions on smoking in indoor areas (including indoor areas of general hospitals and residential health care facilities) are contained in a separate section and are not changed. This is one of the first laws to prohibit smoking outdoors.

Hospitals and residential care facilities should have policies in place to comply with the law.

SAFE Act Requirement That Mental Health Professionals Report Conduct That Would Result in Serious Harm

The New York Secure Ammunition and Firearms Security (SAFE) Act, signed into law after the Sandy Hook school tragedy, is a gun control statute that requires mental health professionals (defined as Physicians, Psychologists, Registered Nurses, and Licensed Clinical Social Workers) who determine that a patient is likely to engage in conduct that would result in serious harm to self or others, to report that information, as soon as practicable, to the director of community services or a designee. This new section in the Mental Hygiene Law was effective March 16, 2013 and applies to all conduct that would result in serious harm to self or others, regardless of whether a legal firearm is implicated. Once the report is made, a determination will be made if the patient reported has

a legal gun, has applied for a gun permit or is prohibited from owning a gun under applicable state or federal law. The SAFE Act reporting requirement does NOT address notification to law enforcement or to a potential victim to warn of a risk of injury to the patient or others.

The New York Psychiatric Association has expressed concern because the statute fails to require that the risk be imminent as well as serious. It has provided members with the following guidance on the reporting requirement currently in force:

> **Office/Outpatient Treatment.** If a psychiatrist determines, using professional medical judgment, that a patient poses a *serious and imminent* risk to self or others that warrants a warning to law enforcement or to a potential target, then the psychiatrist should also submit a SAFE Act report. Therefore, in this situation, we recommend the following steps:
>
> 1. Contact law enforcement and, where appropriate, a hospital's emergency department, to have the patient brought to the hospital for evaluation.
> 2. Notify a potential victim, where applicable.
> 3. Submit a report to the online Integrated SAFE Act Reporting Site (ISARS) (http://www.omh.ny.gov/omhweb/safe_act/).
>
> In the past, if a psychiatrist knew that a patient was about to be involuntarily hospitalized, the psychiatrist may have determined that there was no immediate duty to warn because the patient would be maintained in a secure environment. However, that reasoning does not necessarily apply with respect to the SAFE Act and a report may be required even in connection with patients about to be admitted to an inpatient facility. As emphasized by OMH, involuntary hospitalization does not vitiate the need to submit a SAFE Act report because the true aim of the statute is not to protect the public from imminent harm but to reduce access to legal firearms.
>
> **Inpatient Treatment.** The greatest impact of the reporting requirement may prove to be in the inpatient treatment setting. In this case, the standard for involuntary hospitalization under MHL §9.39 and MHL §9.45 are substantially similar to the "likely to result in serious harm" standard used in the SAFE Act. As a result, if a patient meets the standard for involuntary hospitalization under MHL §9.39 or MHL §9.45, the patient would meet the standard for an MHL §9.46 report. Although there is a discernible distinction between the OMH involuntary hospitalization standard and the generally accepted standard for making a warning in the event of "serious and imminent danger" (see MHL §33.13(c)(6)), it is reasonable to conclude that anyone involuntarily hospitalized under MHL §9.45 or MHL §9.39 also meets the standard for reporting under the SAFE Act.
>
> In addition, a person who is admitted on a voluntary basis may nevertheless meet the MHL §9.46 standard and a SAFE Act report would be required. On the other hand, the fact that a patient has been hospitalized (whether voluntary, involuntary or informal) does not itself trigger an obligation to contact law enforcement or an endangered individual.
>
> Finally, no SAFE Act reporting would necessarily be required where a patient was involuntarily hospitalized based upon the MHL §9.27 standard of "in need of involuntary care and treatment," i.e., a patient "whose judgment is so impaired that he is unable to understand the need for such care and treatment." There is no need to file a SAFE Act report upon discharge because an individual should not, at discharge, present a risk of harm to self or others.

Reporting is not required if the mental health professional believes, in the exercise of reasonable professional judgment, that doing so would endanger the mental health professional or increase the danger to a potential victim or victims.

Individuals who are the subject of a report will not have access to the report or to the reporter's name or contact information, including through FOIL requests. However, patients *may* learn that a report was made if they request a copy of their medical record. Mental health professionals may, but are not required to, inform the patient of their decision to file a SAFE Act report.

Mental health professionals, and health care entities employing mental health professionals should have policies and procedures in place to implement SAFE Act reporting.

Medical Marijuana

Editor's note: This edition of the Journal *carries a more comprehensive summary of New York's new medical marijuana law starting on page 42.*

On July 5, 2014, Gov. Andrew Cuomo signed a limited medical marijuana bill into law. With passage of the Compassionate Care Act, New York is now the 23rd state with an effective medical marijuana law.

It is not expected that the medical marijuana program will begin for at least 18 months as state officials decide

on specifics, such as distributing licenses and where to place dispensaries. Five regulated manufacturers will be selected to grow marijuana within New York, with each able to operate four dispensaries. Medical marijuana can only be distributed through licensed dispensaries (exact locations have not yet been determined).

In order to be prescribed medical marijuana, a patient must receive a certification from a licensed and qualified practitioner who must register with the Department of Health. Registry identification cards will be issued by the DOH to certified patients.

Medical marijuana will be available for a host of serious conditions, including cancer, HIV/AIDS, ALS (Lou Gehrig's Disease), Parkinson's Disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with objective neurological indication on intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's Disease, or as added by the commissioner by DOH. Patients may not smoke medical marijuana. It will be available only through alternatives forms, such as edibles, oils and vaporizers, in forms determined by the state health commissioner.

Health insurers are not required to provide coverage for medical marijuana.

Hepatitis C Screening Must Be Offered

On October 23, 2013, Governor Andrew M. Cuomo signed into law a new Section 2171 of the Public Health Law that requires the offering of a hepatitis C screening test to every individual born between 1945 and 1965 receiving inpatient hospital care or primary care. The CDC estimates that an estimated 2.7 million to 3.9 million people are living with hepatitis C virus (HCV) infection and that up to 75% of persons living with HCV do not know their status.

The New York State Hepatitis C Testing Law applies to anyone born between 1945 and 1965 receiving health services as an inpatient of a hospital or receiving primary care services in the outpatient department of a hospital or in a freestanding diagnostic and treatment center or from a physician, physician assistant, or nurse practitioner providing primary care unless the health care practitioner providing such services reasonably believes that:

- The individual is being treated for a life-threatening emergency; or
- The individual has previously been offered or has been the subject of a hepatitis C screening test (except that a test shall be offered if otherwise indicated); or
- The individual lacks capacity to consent to a hepatitis C screening test.

If an individual accepts the test offer and the screening test is reactive, the health care provider must either offer the individual follow-up health care or referral to a health care provider who can provide such care, including a hepatitis C diagnostic test.

The offer of testing must be culturally and linguistically appropriate in accordance with rules and regulations promulgated by the Commissioner of Health.

Changes to HIV Testing Consent

As of April 1, 2014, New York State allows for streamlined oral patient consent to an HIV test. The law no longer requires that patient consent be obtained in writing, except in correctional facilities. HIV testing providers must still inform patients prior to conducting an HIV test and must document every HIV test in the patient medical record. Providers must also give the patient key points about HIV testing either verbally, in writing or by video before the test. Consent is durable until revoked.

In addition, authorized state and local health department staff are now permitted to use information obtained via the state HIV/ADIS case reporting to follow up with medical providers regarding linkage to care and retention in care. This is for purposes of identifying patients who may have fallen out of care and allow follow up with health departments.

Margaret J. Davino

Margie Davino took office as Chair of the Health Law Section on June 1, 2014. She is a partner in Kaufman, Borgeest and Ryan, LLP. **See Newsflash, page 72.**

In the New York State Courts

By Leonard M. Rosenberg

Appellate Division Holds That Health Care Providers Have a Private Right of Action Under New York's Prompt Pay Law

Maimonides Medical Center v. First United American Life Insurance Company, 116 A.D.3d 201 (2d Dep't 2014). Plaintiff is a not-for-profit hospital that treated patients insured by Defendant through its supplemental Medicare insurance policies from 2007 through 2011. Plaintiff billed more than $19 million for services rendered to these patients, and in response, Defendant paid slightly over $4 million. Defendant allegedly did not, however, provide any statement explaining why it denied nearly $15 million in reimbursement. Insurance Law § 3224-a, known as the "Prompt Pay Law," requires health insurers to pay undisputed claims within 30 days of receipt by electronic submission, or within 45 days if sent by other means. If the insurer denies the claim, in whole or in part, it must pay any undisputed portion of the claim and, within 30 days, provide written notification explaining the specific reason for the denial. The insurer can alternatively request additional information necessary to determine its liability. Failure to comply with this rule entitles the provider to the full amount of the claim, plus interest of at least 12% per annum.

Plaintiff brought this action in Supreme Court, Kings County, claiming breach of contract, unjust enrichment, and violation of the Prompt Pay Law. Defendant moved to dismiss, asserting that the Prompt Pay Law does not provide a private right of action. The Supreme Court denied Defendant's motion to the extent that it sought dismissal of these claims, holding that a close reading of the statute reveals an express legislative intent to confer a private right of action on providers and patients. Defendant appealed.

The Appellate Division, Second Department did not find an express private right of action in the language of the statute, but it held that a private right of action was fairly implied. The Court began its inquiry with the three-factor test annunciated by the Court of Appeals in *Carrier v. Salvation Army*: (1) whether the plaintiff was among the statute's intended beneficiaries, (2) whether a private right of action would promote the legislative purpose, and (3) whether a private right of action is consistent with the legislative scheme. Defendant challenged only the third factor, which *Carrier* deemed the "most critical." Defendant relied on the fact that enforcement of violations of the Insurance Law is vested in the Superintendent of Insurance. In addition to the general enforcement provisions, a related bill passed on the same day authorizes the Superintendent to impose a civil penalty of up to $500 per day of noncompliance with the Prompt Pay Law, not to exceed $5,000.

Nevertheless, the Court found Defendant's argument unpersuasive. After parsing the language of the statute, it found that unlike many provisions of the Insurance Law, which are remedial in nature, the Prompt Pay Law imposes specific duties upon insurers and creates rights for patients and providers. The Court found further support for this holding in *Henry v. Isaac*, where it found an implied private right of action under Social Services Law article 7. The Court also reviewed the legislative history and noted that the Prompt Pay Law was intended to protect patients and providers from late payments. Because the Superintendent does not distribute fines to providers or patients, the Court held that the administrative remedies do not adequately provide such protection.

The Court was equally unsympathetic to the arguments of amicus curiae in the insurance industry. The Court noted that the industry urged veto of the bill when it was passed by the Legislature in 1997, contending that a private right of action might be implied. The Court also rejected the argument that private enforcement would force the Courts to settle insurance disputes without agency expertise, as the statute has an "easily determinable standard" for violations and a provision for liquidated damages.

Defendant further argued that the Court should follow *Group Health, Inc. v. Kofinas*, which specifically held that there is no private right of action under the Prompt Pay Law. However, the Court asserted that *Kofinas* relied entirely on a Second Department decision—holding that a private right of action cannot be implied where there is a potent official enforcement mechanism—which was explicitly overturned by a subsequent decision of the Court. A similar holding in *Klinger v. Allstate Ins. Co.*, upon which amicus curiae relied, was also overturned by a subsequent decision of the Second Department, which noted that the potency of the enforcement mechanism is a factor but not dispositive.

Lastly, the Court rejected Defendant's contention that there could be no implied private right of action because of several unsuccessful attempts by legislators to pass an express private right of action. Relying on *Henry*, the Court held that where there is no express private right of action, it is a matter for the Courts, not the Legislature, to determine whether a private right of action is implied.

Second Circuit Denies Provider's Request to Arbitrate Fraud and RICO Claims Based on No-Fault Overpayment

Allstate Insurance Company v. M.D. David Mun and Nara Rehab Medical, P.C., 751 F.3d 94 (2d Cir. 2014). Defendants are a physician and a medical clinic that billed and collected roughly $500,000 for "Electrodiagnostic Testing" allegedly performed on persons covered under Plaintiff's no-fault insurance policies. Pursuant to the 30-day payment requirement under the no-fault insurance regime, Plaintiff timely paid all these claims, but later on believed that Defendants had fraudulently billed for these tests, as they were either "fabricated or of no diagnostic value."

In August 2012, Plaintiff filed suit in the U.S. District Court for the Eastern District of New York, seeking recovery of the amounts paid upon theories of common-law fraud, unjust enrichment, and violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO"). Defendants moved to compel arbitration pursuant to the arbitration clauses in Plaintiff's no-fault insurance policies and under the New York Insurance Law. The District Court denied Defendants' motion, holding that providers have the right to arbitrate disputed claims that have not been paid, but not actions brought by insurers seeking reimbursement of timely submitted payments. Defendants appealed.

The Second Circuit reviewed the arbitration mechanism under Insurance Law § 5106(b) and its implementing regulations, which give a claimant seeking reimbursement for basic economic loss the right to arbitrate the dispute under "simplified procedures to be promulgated or approved by the superintendent." The Court concluded that the arbitration clauses in the Allstate policies merely incorporated this statutory provision in substance. Although the Federal Arbitration Act expresses a presumption in favor of arbitration, the Court asserted that this presumption applies only where there is a judicial conclusion that the parties intended to arbitrate the particular type of dispute at bar. As the arbitration clauses in the policies merely reflected the statutory scheme, the Court found that Defendants were not "making a claim for first-party benefits" and rejected Defendants' request to arbitrate by contractual right.

The Court employed a similar analysis to Defendants' contention that it had a statutory right to arbitrate the dispute. The Court held that Defendants were not "claimants" under the no-fault scheme in a dispute involving liability to the insurer based upon a fraud theory, years after they timely received payment of their claims. The Court also found persuasive that the arbitration provision specifically references Insurance Law § 5106(a), which provides the 30-day timeline for payment of no-fault benefits, reasoning that the arbitration mechanism is only available to settle disputes arising during that initial period. The Court noted that this connection between subsections (a) and (b) of the statute work together to provide a simple and efficient system for claimants to receive payments that were initially denied. Complex fraud and RICO issues, the Court held, are inappropriate for such a system.

Moreover, the Court asserted that allowing providers to arbitrate fraud disputes would undermine anti-fraud measures that the Legislature has encouraged. The Court relied on a letter from the Supervising Attorney of the Department of Insurance to Plaintiff's counsel, arguing that the no-fault system, which was created to benefit consumers, would be weakened by a holding that the statute bars the availability of judicial recourse for the reimbursement of fraudulently obtained benefits.

Contract for Software-Based Billing, Collection, and Administrative Services Found to Be "for Service to or for Personal Property" Under General Obligations Law § 5-903(2), Thus Requiring Prior Written Notice for Automatic Renewal to Be Effective

Healthcare I.Q. v. Dr. Tsai Chung Chao, MD, doing business as Naruto-Medical Health Care, P.C., 118 A.D.3d 98 (1st Dep't 2014). In February 2007, Plaintiff, a health care service company, entered into a three-year contract with Defendants, a physician and his professional corporation, for billing, collection, and management services through a proprietary software program. The agreement contained a license to use the software, as well as a business associate addendum pursuant to HIPAA requiring the return or destruction of Protected Health Information upon the agreement's termination. Under the agreement, Defendants were required to upload all of their records to the program, including HIPAA-protected patient information, which Plaintiff would then use to perform its services.

The agreement further had an automatic renewal clause, such that at the expiration of the initial term it would renew for an additional eighteen months absent written notice by either party. In early 2010, Plaintiff and Defendants informally discussed renewal, but no party provided written notification of its intent to renew or terminate the agreement. After February 2010, Defendants stopped making payments to Plaintiff and uploading their medical records, but they continued to access Plaintiff's program in order to view their past patient records. Pursuant to the business associate addendum to the agreement, Plaintiff demanded return of these records.

Plaintiff brought a breach of contract action against Defendants in Supreme Court, New York County.

Defendants sought summary judgment under General Obligations Law § 5-903(2), which renders an automatic renewal clause unenforceable in contracts for "service…to or for…personal property" absent timely written notice from the service provider drawing attention to the provision, which the Supreme Court denied.

Analyzing General Obligations Law § 5-903, the Appellate Division, First Department noted that "personal property" was not defined in the statute, but that Courts have interpreted it to include intellectual property. Further, because the statute is remedial in nature and is intended to "protect service recipients from the harm of unintended automatic renewals of contracts for consecutive periods," the Court asserted that it should be construed broadly.

The Court held that the agreement between the parties was a contract for service to or for personal property as contemplated by the statute. The Court asserted that the billing and medical records were personal property, as they existed separately and apart from the program to which Defendants uploaded them, even though such records existed in electronic form. The Court further noted that under the agreement, Plaintiff took dominion over, maintained, and organized the records in order to provide its services. The Court rejected Plaintiff's argument that its services were consulting and administrative in nature, as the agreement required Defendants to upload all of their paper and electronic claims and all of their explanation of benefit forms in order for Plaintiff to provide its services. The Court concluded that this gave Plaintiff a "level of unfettered use, access, physical possession and management" that "exceeds the scope of incidental information provided for consulting and administrative services."

Because Plaintiff failed to provide advance written notice of the automatic renewal clause, the Court held that the contract did not automatically renew in February 2010. Furthermore, the Court asserted that Plaintiff's use of the program thereafter did not constitute a breach because it stopped uploading documents and merely accessed patient records that were neither returned nor destroyed pursuant to the business associate addendum to the agreement.

Appellate Division Holds That Remedy for Hospital's Involuntary Retention of Patient Beyond the Retention Time Period Set by Court Order Is a Hearing, Not the Immediate Release of the Patient

People ex rel. DeLia v. Munsey, 117 A.D.3d 84, 983 N.Y.S.2d (2d Dep't 2014). Appellant, a private psychiatric hospital, appealed the judgment of the trial Court, which ordered the release of an involuntarily retained patient, without a hearing, based on the hospital's failure to timely file an application to retain the patient. Reversing the decision of the trial Court, the Appellate Division, Second Department, held that despite the hospital's failure to timely comply with the procedures set forth in the Mental Hygiene Law, the trial Court was nevertheless required to conduct an examination into the patient's alleged mental disability and detention.

The patient was involuntarily admitted to a private psychiatric hospital by the New York State Office of Mental Health. After the patient's three-month psychiatric admission period expired, Mental Hygiene Legal Services ("MHLS") filed a writ for habeas corpus pursuant to Article 70 of the CPLR, alleging that the hospital was illegally detaining the patient. In response, the hospital applied for authorization to further involuntarily retain the patient pursuant to article 9 of the Mental Hygiene Law. In support of the hospital's application, the hospital submitted two medical certifications averring that the patient was paranoid, unable to care for himself, and dangerously assaultive. Specifically, the hospital reported that the patient stabbed a hospital staff member in the neck with a pen and attacked a psychiatrist by choking him and punching him in the face.

When the patient was produced before the Court, MHLS sought the patient's immediate discharge on the basis that the hospital had wrongfully detained the patient beyond the end of the patient's retention period. In response, counsel for the hospital argued that the controlling precedent provided that the remedy for such administrative error was not the immediate release of the patient, but a substantive hearing to determine whether continued retention was warranted. Following oral argument, the judge ordered the hospital to discharge the patient. The order was stayed pending appeal; five months later, the patient was discharged.

On appeal, the Court considered two questions: (i) whether the Supreme Court may grant a patient's petition for a writ of habeas corpus and deny a hospital's untimely involuntary retention application without first conducting a hearing as to the patient's alleged mental disability and detention, and (ii) whether a writ of habeas corpus filed pursuant to article 70 is substantively different from a petition for a writ brought under Mental Hygiene Law § 33.15.

The Court answered both questions in the negative. Although the Court noted that the fact that the patient is no longer admitted at the hospital renders the appeal academic, the Court considered the case an exception to the mootness doctrine because the issue raised implicates the patient's fundamental liberty interest, the State's interest in protecting the mentally ill, and is one that is likely to occur. Turning to the primary issue, the Court held that there is no dispute that the hospital failed to comply with the Mental Hygiene Law's requirement that it seek an order authorizing an additional period of retention prior to the expiration of the patient's current admission period. However, that did not end the Court's inquiry. In order to determine whether the trial Court properly

ordered the patient's immediate release, the Court held that it must first review the applicable constitutional and statutory framework.

Construing the habeas corpus provisions of CPLR article 70 and the Mental Hygiene Law, the Court noted that Mental Hygiene Law § 33.15 expressly requires the Court to "examine the facts concerning the patient's alleged mental disability and detention" upon the return of the writ of habeas corpus. The Court then examined three cases in detail, all of which concluded that despite the hospital's failure to timely file an application for the continued retention of a psychiatric patient, the Court must first examine the merits of the hospital's retention application before directing the release of the patient. Based on this precedent, the Court held that the trial Court erred in ordering the release of the patient without first conducting an examination into the patient's alleged mental disability and detention.

Turning to the second issue, the Court rejected MHLS's argument that because the petition was filed under CPLR article 70, the provisions set forth in Mental Hygiene Law § 33.15, requiring an examination into the patient's alleged mental disability, are inapplicable. The Court held that because Mental Hygiene Law § 33.15 is the more specific statute, and is directed exclusively to those retained in psychiatric facilities, the provisions of Mental Hygiene Law § 33.15 are controlling in mental hygiene cases. Indeed, the Court noted that a contrary determination would frustrate the legislative intent that an examination be conducted when a psychiatric patient seeks habeas corpus relief, and that the patient be discharged only if the Court finds that the patient is not mentally disabled or in need of further retention for in-patient care and treatment.

Finally, the Court cautioned that its determination should not be viewed as an approval of the Hospital's "dilatory conduct in filing the retention application," and should not be construed as to authorize an unlimited violation of article 9 of the Mental Hygiene law so that a patient may be involuntarily retained, without a hearing, indefinitely.

Court Rules That Six-Year Statute of Limitations Applies to Bar Provider from Recouping Overpayments Paid Under Public Health Law § 2807-j

New York Med. & Diagnostic Ctr., Inc. v. Shah, 116 A.D.3d 862, 984 N.Y.S.2d 383 (2d Dep't 2014). Petitioner, a diagnostic and treatment center, brought an Article 78 proceeding seeking a judgment declaring that the New York State Department of Health ("DOH") improperly relied on a six-year statute of limitations in denying Petitioner a full refund for overpayments it allegedly made to the DOH. Reversing the decision of the trial Court, the Appellate Division, Second Department, held that the lower Court erred in finding arbitrary, capricious and irrational the DOH's interpretation that Public Health Law § 2807-j(8-a)(a) imposed a six-year statute of limitations on Petitioner's request for a refund of overpayments.

In an effort to improve the accessibility and affordability of health care throughout the State, the New York Health Care Reform Act of 1996 requires that designated providers of medical services pay a surcharge on payments made for services rendered in general hospitals and certain diagnostic and treatment centers. The surcharge is paid to a public pool established by the Public Health Law. These payments must be submitted, with limited exceptions, to the Commissioner of the DOH on a monthly basis. Pursuant to Public Health Law § 2807-j (8)(c), when an overpayment is made, the overpayment shall be applied to any other payment due, or if no payment is due, shall be applied to future payments or refunded to the provider.

Public Health Law § 2807-j (8-a)(a) also provides that payments and reports "shall be subject to an audit by the Commissioner for a period of six years following the close of the calendar year in which such payments and reports are due, after which such payments shall be deemed final and not subject to further adjustment or reconciliation." Giving "plain meaning" to the language of this section, the Second Department held that the DOH's determination to apply a six-year limitations period to Petitioner's application for a refund for an overpayment was not arbitrary, capricious or irrational.

In reaching its decision, the Court also held, in contrast to the reasoning of the trial Court, that the absence of any reference to such limitation period in Public Health Law § 2807-j(8)(c), the section of the statute that addresses requests for an overpayment refund, does not compel the conclusion that the six year period contained in Public Health Law § 2807-j(8-a)(a) is inapplicable to such requests.

Third Department Upholds the Administrative Review Board for Professional Medical Conduct's Revocation of a Physician's License Following a Conviction for Federal Health Care Fraud

Matter of Mark X. Huang v. Administrative Review Board for Professional Medical Conduct, 114 A.D.3d 1103 (3d Dep't 2014). In 2009, Mark X. Huang ("Petitioner"), a physician licensed to practice medicine in New York, pled guilty to federal health care fraud involving the falsification of claims valued at over $2.5 million. As a result of the conviction, Petitioner was sentenced to a prison term of 12 months and one day and was required to pay restitution and a fine, with the prison term to be suspended if Petitioner paid at least $2 million in restitution within eight months. Petitioner made the required payments within eight months, and was placed on super-

vised release for a period of three years. Thereafter, pursuant to New York Public Health Law § 230(10)(p), the Bureau of Professional Medical Conduct ("BPMC") commenced a direct referral proceeding alleging professional misconduct based upon the conviction. A Hearing Committee of the State Board for Professional Medical Conduct sustained the charge and suspended Petitioner's medical license for a period of nine months and imposed monitoring and continuing medical education requirements. The BPMC petitioned for review, and the Administrative Review Board for Professional Medical Conduct ("ARB") revoked Petitioner's license to practice medicine. Petitioner then commenced this proceeding seeking to annul the ARB's determination, arguing that the ARB improperly revoked his license as an "automatic" consequence of his conviction, thereby impermissibly usurping a legislative function and violating Petitioner's substantive due process rights.

The Court held that the ARB's determination was not an "automatic" consequence of Petitioner's conviction, but was rather premised on the particular characteristics of the crime, including the magnitude of the fraud ($2.5 million), the duration of the fraud (5 years), and Petitioner's knowledge that the conduct was wrong. The Third Department also found that the ARB had weighed potential mitigating circumstances.

In addition, the Court held that the ARB is "vested with the authority to review a penalty…and it is empowered to substitute its judgment for that of the Hearing Committee and impose a harsher sanction." The Third Department went on to state that the Court's review of ARB determinations is generally limited to whether the penalty is so "disproportionate to the offense that it shocks one's sense of fairness." Here, the Court found no such grounds and further rejected Petitioner's claim that the ARB's determination that Petitioner "preyed upon his patients" was unsupported by the record. Accordingly, the Third Department confirmed the revocation of Petitioner's license.

Appellate Division Rules That OMIG May Rationally Exclude a Physician from Medicaid Based on a Criminal Conviction Even Though OPMC Took No Disciplinary Action

Andries v. Cox, 117 A.D.3d 731, 985 N.Y.S.2d 155 (2d Dep't 2014). The Office of the Medicaid Inspector General ("OMIG") excluded petitioner from participating in the New York State Medicaid Program after he plead guilty to a single felony count of distribution of misbranded prescription drugs. The plea was a satisfaction of charges that petitioner sold prescription drugs to patients over the internet without medically evaluating them. OMIG did not set any end date for the exclusion. The New York State Board of Professional Medical Conduct declined to take any action against petitioner's medical license.

Following petitioner's administrative appeal, which was denied, petitioner commenced a CPLR article 78 proceeding to review OMIG's determination. The Supreme Court granted the petition to the extent of modifying the penalty imposed so as to permit the petitioner to make an immediate application for reinstatement in the Medicaid program. Furthermore, the Supreme Court directed OMIG to "make its written determination as to petitioner's immediate reinstatement, or…provide a date certain for reinstatement, or describe with sufficient particularity the conditions to be met in order for petitioner to qualify for reinstatement."

However, the Court rejected petitioner's contention that it was arbitrary for OMIG to exclude him when the New York State Board of Professional Medical Conduct had declined to sanction him. The Court held that OMIG's determination was rationally based on 18 NYCRR 515.7 (c), which authorizes OMIG to exclude physicians from Medicaid that have been convicted of a crime relating to "the furnishing of or billing for medical care, services or supplies…or participation in the performance of management or administrative services relating to furnishing medical care, services or supplies."

The Court affirmed the lower court's ruling that OMIG must include provisions regarding the timing and conditions of petitioner's reinstatement in the Medicaid program. Pursuant to New York State law (18 NYCRR 515.6[b][2][iv]), OMIG's notice of exclusion must state the earliest date on which a request for reinstatement may be made.

First Department Holds That Statutory Requirement for OPMC to Submit Investigation Results to a Committee Within 90 Days of Most Recent Interview Is Directory, Not Mandatory; Denies Bid to Dismiss Investigation for Non-Compliance

In re Patel v. Shah, 115 A.D.3d 559 (1st Dep't 2014). Physician-petitioner Kaplana Patel, M.D. ("Petitioner"), was the subject of an investigation by the OPMC. Arguing that OPMC violated New York Public Health Law ("PHL") § 230(10)(a)(iii)(C), which requires the OPMC to submit its investigation to an investigation committee within the 90 days following the OPMC's most recent interview of the subject physician, Petitioner moved for a writ of mandamus compelling the OPMC to dismiss the investigation, and for a writ of prohibition barring the OPMC and its agents from acting or causing anyone else to act on the basis of any information obtained through the investigation.

In declining to adopt Petitioner's argument, the First Department held that PHL § 230(10)(a)(iii)(C) is not "strictly mandatory," given that PHL § 230(10)(j) affords a licensee the ability to commence an article 78 proceeding challenging the OPMC's non-compliance with the 90 day time limit. At such article 78 proceeding,

the licensee is required to show that it neither caused the delay nor was prejudiced by the delay, so long as a respondent meets its initial burden to explain its noncompliance. Here, the Court found that PHL § 230(10)(j) supplied Petitioner with an "adequate remedy at law." Thus, the Court held that Petitioner failed to establish, as is her burden, a "clear legal right" to relief for either a writ of mandamus or a writ of prohibition. In support of its holding, the First Department cited *Matter of Brusco v. Braun*, 84 N.Y.2d 674, 679 (1994) and *Matter of Doe v. Axelrod*, 71 N.Y.2d 484, 490 (1988) for the proposition that writs of mandamus and prohibition are extraordinary remedies and also that a writ of prohibition is not a means of collateral review of an administrative process.

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In the New York State Legislature

By James W. Lytle

Introduction

During the course of the 2014 legislative session, 658 bills passed both houses, seven more than last year, but continued a trend of relatively few bills passing the Legislature and reaching the Governor during recent years. The below bills are those passed that may relate to issues of interest to lawyers representing health and human services clients.

Aging Services

Criminal History Check of Adult Home Employees (A.5476-D Cymbrowitz / S.4926-C Hannon): This bill would make technical amendments to section 38 of Part A of the laws of 2013, requiring the Department of Health (DOH) to conduct a criminal history record review of all prospective employees of an adult care facility. This bill would delay implementation of the law and clarify that the 2013 law applies to all adult care facilities regulated by DOH. This bill was signed into law by the Governor on July 22. This bill took effect immediately, provided that certain provisions would take effect on January 1, 2015.

Disclosure in Advertisements on Senior Issues (A.1787-C Millman / S.7254-A Valesky): This bill would require individuals or businesses who are holding themselves out as offering services or credentials that are senior-specific to offer proof of such specialization or credentials in advertisements and during the initial consultation for services. This would ensure that individuals or business cannot falsely portray themselves to seniors as providers of specialized advice or services at an increased cost. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Ability of CCRC's to Provide Home Care Services (A.4611-B Schimminger / S.2118-B Ranzenhofer): This bill would allow continuing care retirement communities (CCRC) to offer home care services to seniors residing outside of the CCRC through a separate corporation that would be licensed through Article 36 of the Public Health Law. This would allow CCRCs to expand their offering beyond the traditional CCRC campus, and give seniors the option of remaining in their homes while taking advantage of the benefits of streamlined services offered by CCRCs. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Assistance for Informal Caregivers (A.8871 Millman / S.7255 Valesky): This bill would require local area agencies on aging to develop guidelines for informal caregivers related to available services for the aging, as well as resource and counseling referrals. This bill was signed into law by the Governor on August 11. This bill took effect immediately.

Chemical Dependence Counseling in NORCs (A.9067 Millman / S.6858 Golden): This bill would allow Naturally Occurring Retirement Communities (NORCs) to offer chemical dependence counseling and referrals to chemical dependence counseling providers as an eligible service. This bill was signed into law by the Governor on August 11. This bill took effect immediately.

Emergency Access for Homecare and Hospice Workers (A.6530-B Cusick / S.4719-B Lanza): This bill would require counties and cities with a population of one million or more to consider the needs of homecare agencies and hospice providers when developing their comprehensive emergency management plans, including access to restricted areas or areas operating under a curfew. This would ensure that home care and hospice workers are able to reach their homebound patients during disasters, thereby decreasing the workload of already taxed emergency personnel. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Energy and Environment

Prohibition on TRIS Use in Child Products (A.4741 Sweeney / S.3703-B Grisanti): This bill would add flame retardant product TRIS (1,3-dichloro-2-propyl) phosphate (TDCPP) to the list of substances prohibited for use in child care products sold or offered for sale in New York State. According to the bill sponsors, TDCPP was previously banned in children's sleepwear by the Consumer Product Safety Commission due to health concerns. The product continues, however, to be used in plastics, resins and polyurethane foams found in car seats and baby products. This bill was signed into law by the Governor on September 18. This bill would take effect on December 1, 2015.

Drug Disposal Demonstration Program (A.5465 Sweeney / S.3985-A Grisanti): This bill would create a drug disposal demonstration program for the take-back of unused or expired pharmaceutical drugs in order to prevent abuse and environmental contamination. The program

requires DEC, in consultation with the State police, to establish a minimum of three disposal sites available at State police facilities. This bill would also require DEC to maintain and make available a list of disposal sites and prepare a report detailing the efficacy of the demonstration program once it has concluded. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately and be deemed repealed on December 31, 2016.

Government Reform

Prompt Pay of Interest to Nonprofits (A.8964 Englebright / S.6482 DeFrancisco): This bill would require state agencies to pay interest owing on payments to nonprofits within 30 days of when the payment is due. Under current law, when state agencies owe money, such as grants, for services provided by nonprofits, the nonprofits are entitled to interest payments from the agency for the period starting with the contract commencement date or the date services are begun, whichever is later, until the date payment is made. There is no requirement as to when the interest payment must be made under existing law. This bill would establish that the interest payment must be made within 30 days of when payment is due. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Nonprofit Employee as Board Director Prohibition Extender (Chapter 81 of the Laws of 2014; S.7799-A Ranzenhofer / A.10027-A Rules, Brennan): This law extends the compliance date by one year—from January 1, 2015 to January 1, 2016—for implementation of the prohibition on employees of nonprofits serving as the Chair on the nonprofit's board of directors. The prohibition was enacted as part of the Not-For-Profit Revitalization Act of 2013, but the Legislature indicated that it required additional time to understand the implications of the prohibition upon nonprofits' operations. This law was signed by the Governor on June 30, 2014, and took effect on that date.

Local Government RFPs on State Procurement Opportunities Newsletter (A.8661-A Paulin / S.6595-A Flanagan): This bill would authorize local governments, including school districts, to post bids for goods and services valued at more than $15,000 in the State Public Opportunities Newsletter, in addition to publishing in local newspapers, as is currently the minimum notice requirement. This bill was signed into law by the Governor on September 23. This bill took effect immediately.

New York State Grants Gateway (A.9599 Brennan / S.7340 Ranzenhofer): This bill would allow nonprofit organizations who are prequalified through the New York State Grants Gateway to maintain their prequalification status while they are in the process of amending their document vault in order to comply with the provisions of the Not-for-Profit Revitalization Act of 2013. Currently, all nonprofit organizations conducting business with or receiving grants from the State must be prequalified in the State's Grants Gateway system. However, when a prequalified nonprofit opens its document vault to amend or update documents, its prequalification status is revoked until the new documents in the vault can be reviewed by the Division of Budget. If these changes need to be made while the nonprofit is in the process of applying for a grant, it could jeopardize their ability to qualify for the grant. This bill would allow any nonprofit that submits the amendments required by the Not-for-Profit Revitalization Act by January 1, 2015 to maintain their prequalification status unless their documents are eventually disapproved. This bill has passed both houses, but has not yet been sent to the Governor. This bill would took effect immediately.

Higher Education

Personal Identifiers of Researchers (A.8109-B Englebright / S.5731-B Flanagan): This bill would allow state agencies to shield the personal information of researchers and institutions of higher education conducting biomedical research or teaching if disclosure of such information could endanger the life or safety of the individual or the security of the institution. These provisions seek to protect individuals and laboratories performing controversial research from intimidation, threats, or violence carried out by individuals or organizations that oppose their work. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Insurance

Coverage of Telehealth Services (A.9129-A Russell / S.7852 Young): This bill would require insurance coverage of any health care services delivered via telemedicine or telehealth, as long as such health care services are otherwise covered under the patient's insurance policy. This bill has passed both houses, but has not yet been delivered to the Governor. This bill would take effect on January 1, 2015.

Insurance Coverage for Ostomies (A.8137-A Magnarelli / S.5937-A Valesky and A.10140 Magnarelli / S.7893 Valesky): These bills would require health insurers and health maintenance organizations to include full coverage of equipment and supplies used to treat ostomies. These bills were signed by the Governor on September 23. These bills take effect on the first January after being enacted and apply to all policies issued, renewed, modified, altered or amended on or after such date.

Health Insurance Demonstration Program Application Process (Chapter 13 of the Laws of 2014; A.8398 Morelle / S.6252 Robach): This law clarifies that a request for approval of a pilot project to provide coverage

to independent workers and former employees must be submitted within 30 days of the effective date of the section. This bill was signed by the Governor on March 17, 2014 and took effect on that date.

Host's Affirmative Duty to Render Assistance (A.3303-B Abbate / S.1178-B Martins): This bill would amend the General Obligations Law to require a social host, who is present and has actual knowledge, to notify emergency responders that a guest on their private premises is suffering or has suffered a medical emergency. This bill has passed both houses, but has not yet been sent to the Governor. The bill would take effect on the sixtieth day after it became law.

Internet Enrollment of New York State Employees (A.9175-A Braunstein / S.6505-B Seward): This bill would amend the Insurance Law to facilitate internet enrollment of a New York State employee who is applying to be covered under a group life, health or annuity contract that has been issued to an out-of state employer by an insurer that is otherwise not authorized to do an insurance business in New York State. This internet enrollment option would only be made available where group insurance standards similar to what are currently required are in effect. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Health Insurers and Affiliate Companies (A.9208 Cahill / S.6960 Seward): This bill would amend the Insurance Law to authorize the Superintendent of Financial Services to approve a request made by a health insurer to satisfy the requirement that they issue replacement coverage in the case of a class discontinuance of individual coverage by way of conversion coverage offered through another entity with the insurer's holding company system. This bill was signed by the Governor on September 23. This bill took effect immediately.

Claim of Medical Professional Misconduct (A.7558-B Barrett / S.7854 Hannon): This bill would amend the Public Health Law to ensure that Office of Professional Medical Conduct shall not identify, investigate or charge a practitioner with misconduct based solely upon the recommendation or provision of care of a treatment modality that is not universally accepted by the medical profession. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Mental Hygiene

Transitional Care (A.9729 Jaffee / S.7374 Bonacic): This bill would remove the requirement that individuals who are receiving transitional care must have aged out of their prior care setting prior to July 1, 1996, and open up transitional care to all individuals aging out of educational services who need continued residential services. This bill would also give parents and other caregivers' due process protections that allow them to appeal the eventual residential placement of these individuals if they feel that the setting is not appropriate. Currently, individuals who reached twenty-one after July 1, 1996 have no right to appeal their residential placement, which is a right granted to all other Office of People with Developmental Disabilities (OPWDD) clients. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

People First Act of 2014 (A.8452 Gunther / S.1109-D Maziarz): This bill would require the Commissioner of OPWDD to conduct a geographic analysis of supports and services in community settings for individuals with developmental disabilities to identify gaps in filling those needs, which would be categorized as "emergency need" (where immediate support is required), "critical need" (which would need to be addressed within a year) and "planning for need" (where the needs are likely to arise between one and five years away or involve caregivers over the age of sixty). This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Task Force on Adults with Developmental Disabilities (A.8835-A Gunther / S.6695-A Carlucci): This bill would establish a task force to develop recommendations on meeting the needs, including the social, vocation, and recreational needs, of adults with developmental disabilities. The recommendations would be submitted to the Governor and to the Legislature by January 1, 2016, and the task force would dissolve two years after this bill is signed into law. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Reform of OPWDD's "Front Door" Initiative (A.8846-A Weisenberg / S.6641-C Carlucci): This bill would require the Commissioner of OPWDD to develop a plan to implement the "front door" process, which would have to be submitted to the Legislature by January 1, 2015, with implementing guidelines in place by April 1, 2015. The guidelines would address the needs of people with developmental disabilities who are living with caregivers whose abilities may be diminished by age, their own disabilities, and other factors and would be required to ensure that critical needs are met on a timely basis. Additionally, waiting lists must be maintained and updated and an appeals process put in place, among many other elements. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Qualifications of Entities in OPWDD's Managed Care Initiative (A.9766-A Gunther / S.7400-B Carlucci): The requirements governing managed care organizations that might enroll persons with developmental disabilities currently mandate that they either have sufficient experience in coordinating services for such persons or affiliate with an entity that does have the requisite experience.

This bill would further require that these affiliating entities be nonprofit entities and that their experience in this field was gained under the regulatory oversight of OPWDD. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Accreditation of General Hospital Outpatient Mental Health and Substance Abuse Services (A.9768-A Gunther / S.7481-A Hannon): Existing law allows the Office of Mental Health (OMH) and Office of Alcoholism and Substance Abuse Services (OASAS) to accept surveys from national accrediting organizations of inpatient mental health and substance abuse services provided by dually certified general hospitals in lieu of their own surveys. This bill would extend these provisions to include outpatient mental health and substance abuse services provided by these hospitals. This bill was signed by the Governor on August 11. This bill took effect immediately.

Justice Center

Technical Amendments to Protection of People with Special Needs Act (A. 9733-A Gunther / S. 7885 Gallivan): This bill, introduced at the request of the Justice Center, would make a series of clarifying and conforming amendments to the Justice Center statute enacted in 2012. The provisions would primarily address provisions in the Social Services Law that govern facilities overseen by the Office of Children and Family Services. This bill was signed by the Governor on July 22. This bill took effect immediately.

Justice Center Protocols for Interviews of Vulnerable Persons (A.9605-A Gunther / S.7232-A Carlucci): This bill would require the Justice Center to develop protocols, in collaboration with the appropriate state agency, to govern the interview of vulnerable persons relating to matters within the jurisdiction of the Justice Center. This bill would require a determination as to whether an interview may be clinically contraindicated. Where interviews are deemed to be appropriate, the Justice Center would develop appropriate procedures and protocols to ensure that the interview occurred in a safe and timely fashion. The protocols and procedures would be required to be developed by January 1, 2015 and implemented by March 1, 2015. This bill was signed by the Governor on September 23.

Public Health

DOH Website to Advance Women's Health (A.4465-A Galef / S.3817 Hannon): This bill would require DOH to develop a website dedicated to raising awareness of women's health issues with a specific focus on promoting the preventive services covered pursuant to federal law and regulation. This bill was signed by the Governor on September 4. This bill took effect immediately.

Eating Disorders Awareness and Prevention (A.5294-A Gunther / S.2530-A Hannon): This bill would require DOH to create an Eating Disorders Awareness and Prevention Program targeting children and adolescents, with a focus on promoting the availability of services and reducing the incidence of eating disorders. This bill was signed by the Governor on September 23. This bill took effect immediately.

Expands the New York State Palliative Care and Education and Training Council (A.9966 Gottfried / S.7601-B Hannon): This bill would require the Commissioner of Health to include two additional participants to the New York State Palliative Care and Education and Training Council. The individuals must be from organizations that are broadly representative of social work and home care. This bill was signed by the Governor on August 11. This bill took effect immediately.

Administration of Hepatitis C Test (A.9124-A Zebrowski / S.6871 Hannon): This bill would allow nurse practitioners and physicians to issue non-patient specific orders for hepatitis C testing. Currently, a registered nurse may offer a hepatitis C test, but then must have a physician or nurse practitioner write a prescription before the test can be performed. Given the new requirement that hepatitis C testing must be offered to all individuals born between 1945 and 1965, this requirement would impact the timeliness of testing and create backlogs. This bill was signed by the Governor on September 16. This bill takes effect 90 days after becoming a law.

Adult Immunization Registry (A.9561 Paulin / S.7253 Hannon): This bill would allow pharmacists and registered nurses who are authorized to administer vaccinations to access the statewide immunization information system, and would also require them to report immunizations given to individuals age nineteen and older, with patient consent. This bill has passed both houses, and was sent to the Governor on October 9. This bill would take effect immediately.

Concussions and New York State TBI Program (A.9651 Benedetto / S.7004-A Young): This bill would require the Traumatic Brain Injury Services Coordinating Council to create a concussion management advisory committee, which would develop a data clearing house, educational programs, and an outreach campaigns related to concussions, and to perform research and investigations relating the cause of prevention of concussions. This bill was signed by the Governor on August 11. This bill took effect immediately.

Hospital Preadmissions and Discharges and Blind or Visually Impaired Patients (A.746-A Rosenthal / S.328-A Avella): This bill would require hospitals to provide blind or visually impaired patients with a large print or audio version of pread-

mission information and discharge plans, with the cost to be borne by the hospital. This bill intends to increase patient adherence to preadmission or discharge instructions by providing them in a format that patients can easily reexamine. This bill was signed by the Governor on July 22. This bill took effect 90 days after becoming a law.

Portable X-Ray Demonstration Program Extension (Chapter 79 of the Laws of 2014, A.10018 Peoples-Stokes / S.7774 Hannon): This law extends for another three years, until June 30, 2017, a demonstration project, first enacted in 1997, that allows for Medicaid reimbursement of portable x-ray services provided to persons who are either home-bound or residents of long term care residential facilities. This law was signed by the Governor on June 30, 2014, and took effect on that date. The law requires an updated report by September 1, 2015.

Enhancing Quality Assurance for Emergency Medical and Trauma Care (A.9611 Gottfried / S.7271 Hannon): This bill would incorporate quality assurance measures into the State's Comprehensive Emergency Medical and Trauma Care plan, and would make autopsy reports relating to persons who die while under hospital care available for quality assurance purposes. This bill was signed by the Governor on September 4. This bill took effect immediately.

21st Century Workgroup for Disease Elimination and Reduction (A.829 Magnarelli / S.2115 Ritchie): This bill would create the 21st Century Workgroup for Disease Elimination and Reduction, which would be comprised of experts on vaccines and immunization. The goal of the workgroup is to modernize DOH's approach to infectious disease management by studying the efficacy of existing and developing vaccinations, and identifying diseases and health threats that could be addressed by the development of a vaccine or changes in immunization schedules. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect 90 days after becoming a law.

Financing Graduate Medical Education and Community Health Initiatives in Rochester Region (A.9421-A Morelle / S.7800 Rules, Robach): This bill would reduce payments by health insurers to hospitals in the Rochester region for Graduate Medical Education (GME) by $100 million and replace that support with an increase in the region's Covered Lives Assessment (CLA)—a per enrollee assessment on health insurance carriers that is part of the State's Health Care Reform Act (HCRA). Beyond the $100 million replacement of the current level of insurance support for GME, the CLA would be increased by an additional $10 million, half of which would be directed toward currently unreimbursed GME expenditures with the balance devoted to community-wide health planning, safety and quality programs, elimination of disparities initiatives, and other community projects. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect on January 1, 2015 and would expire with the expiration of HCRA at the end of 2016.

Maternal Depression Screening and Education (A.9610-B Gottfried / S.7243 Krueger): This bill would establish evidence-based guidelines for maternal depression screening provided by maternal health care providers and pediatric primary care providers. The guidelines would include appropriate diagnostic tools and referral mechanisms for further evaluation. This bill would also direct the health care and wellness education and outreach program within DOH to conduct education and outreach pertaining to maternal depression. Hospitals would also be required to provide information on maternal depression as part of state-mandated maternity care. Additionally, this bill would amend the Insurance Law to provide requirements for the coverage of screening for material depression if it is provided in the insured's policy. A similar bill was vetoed last year on technical grounds, and this bill, which contains amendments requested by the Governor. This bill was signed by the Governor on August 4. This bill took effect immediately.

Heroin and Opioid Abuse Legislative Package

As part of an eleven-bill package enacted at the end of the legislative session, the Legislature passed four bills that addressed the criminal justice aspects of the upsurge in heroin abuse:

Fraud and Deceit Related to Controlled Substances (Chapter 36 of 2014; A.10155 People-Stokes / S.7907 Marcellino): This law establishes a new offense of Fraud and Deceit Related to Controlled Substances, a Class A Misdemeanor, aimed at persons who might seek to obtain a prescription for a controlled substance by fraud or deceit. This includes (i) representing themselves as manufacturers, distributors, pharmacies, or practitioners, (ii) unlawfully possessing a blank official New York State prescription form, or (iii) if a patient fails to disclose that he or she has already been issued a prescription for a controlled substance when issued a new prescription for a controlled substance. This law was signed by the Governor on June 23, 2014, and took effect on that date.

Criminal Sale of a Controlled Substance by a Practitioner or Pharmacist (Chapter 31 of the Laws of 2014; A.10154 Hennessey / S.7902 Hannon): This law adds the offense of Criminal Sale of a Controlled Substance by a Practitioner or Pharmacist to an existing crime (Penal Law §220.65) to make the knowing and unlawful sale of a controlled substance by pharmacists and practitioners a Class C Felony. This law was signed by the Governor on June 23, 2014, and took effect on that date.

Eavesdropping and Surveillance Warrants for Criminal Sale (Chapter 37 of the Laws of 2014; A.10157 Stirpe / S.7908 Hannon): This law adds the newly amended crime of Criminal Sale of a Controlled Substance by a Practitioner or Pharmacist to the categories of crimes for which eavesdropping and surveillance warrants may be issued and within the category of criminal activity that may constitute "enterprise corruption." This law was signed by the Governor on June 23, 2014, and took effect on that date.

Access to Criminal History Information (Chapter 35 of the Laws of 2014; A.10158 Cymbrowitz / S.7906 Martins): This law enhances the investigation capabilities of the Bureau of Narcotic Enforcement in DOH by granting the Bureau of Narcotic Enforcement access to criminal history information maintained by the Division of Criminal Justice Services. This law was signed by the Governor on June 23, 2014, and took effect on that date.

Six bills were included within the package of bills that addressed treatment, education, and outreach efforts:

Heroin and Opioid Addiction Wraparound Services (Chapter 32 of the Laws of 2014; A.10160 Gunther / S.7903 Carlucci): This law establishes a heroin and opioid addiction wraparound services demonstration program, which includes a range of educational, legal, financial and social services during treatment and the nine month period thereafter. This law was signed by the Governor on June 23, 2014, and took effect on that date. The law will be deemed expired and repealed on June 23, 2017.

Opioid Addiction Treatment and Hospital Diversion Program (Chapter 33 of the Laws of 2014; A.10159 McDonald / S.7904 Hannon): This law creates an Opioid Addiction Treatment and Hospital Diversion Program, and utilizes short-term, residential and peer-supported services, together with family supports. This law was signed by the Governor on June 23, 2014, and took effect on that date. The law will be deemed expired and repealed on June 23, 2017.

Heroin and Opioid Addiction Awareness and Education Program (Chapter 40 of the Laws of 2014; A.10161 Cymbrowitz / S.7911 Boyle): This law establishes a Heroin and Opioid Addiction Awareness and Education Program, under the auspices of the Commissioner of OASAS, in cooperation with the Commissioner of Health, that utilizes public forums, social and mass media and other means to educate youth, parents and the general public regarding addiction. This law was signed by the Governor on June 23, 2014, and took effect on that date.

Alcohol, Tobacco and Drug Abuse Educational Information (Chapter 39 of the Laws of 2014; A.10163 Cymbrowitz / S.7910 Martins): This law requires the Commissioner of Education, in collaboration with OASAS and DOH, to modernize alcohol, tobacco and drug abuse educational information, including information relating to abuse of heroin and opioids. This law was signed by the Governor on June 23, 2014, and took effect on that date.

Persons in Need of Supervision (Chapter 38 of the Laws of 2014; A.10162 Lupardo / S.7909 Felder): This law allows for assessment of children that may be considered Persons in Need of Supervision to determine whether they have a substance abuse disorder. This law was signed by the Governor on June 23, 2014, and will take effect on December 20, 2014.

Opioid Antagonists Information Card (Chapter 34 of the Laws of 2014; A.10156 Dinowitz / S.7905 Marchione): This law requires the publication and distribution of an informational card relating to the use of opioid antagonists, which will be made available to opioid overdose prevention programs and includes information about recognizing symptoms of overdose and steps to be taken prior to and after an opioid antagonist is administered. This law was signed by the Governor on June 23, 2014, and took effect on that date.

The final bill addressed insurance coverage of substance abuse disorders:

Insurance Coverage of Substance Abuse Disorders (Chapter 41 of the Laws of 2014; A.10164 Cusick / S.7912 Robach): This law addresses coverage of substance abuse disorders (SUDs) by health insurers. Specifically, the law (i) strengthens existing SUD coverage mandates, aligning existing requirements with federal mental health parity requirements; (ii) enhances utilization review (UR) requirements concerning qualifications of clinical reviewers, clinical review criteria, and the expedition with which UR decisions are made, as well as mandates coverage while such decisions are pending; (iii) clarifies regulatory enforcement obligations with respect to these reforms; and (iv) creates an SUD workgroup to study and make recommendations. This law was signed by the Governor on June 23, 2014. Provisions regarding SUD coverage and UR will generally take effect on April 1, 2015 and apply to policies issued, renewed, modified, altered or amended on and after such date. The coverage requirements will apply to commercial health insurance policies, including those offered through the State's health benefit exchange, while the utilization review requirements would be applicable across the board to both commercial and Medicaid health plan coverage. Provisions regarding the workgroup and enforcement by the Superintendent of Financial Services took effect on June 23rd.

Pharmacy-Related

Caregivers and Prescription Refills (A.8612-A McDonald / S.6449-A Hannon): This bill would prohibit pharmacies from automatically delivering new or existing prescriptions offsite without the consent of a patient or their caregiver. If the pharma-

cy delivers a prescription without the patient or their caregiver's consent, then the pharmacy would be obligated to take the prescription back, refund any payments, and destroy the medication. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Household Pharmaceutical Collection Events (A.1609 Cymbrowitz / S.6691 Boyle): This bill would require OASAS, in cooperating with DEC, to provide website information on the required guidelines for household pharmaceutical collection events, aimed at encouraging the proper disposal of unused or expired medications in order to prevent diversion and abuse. This bill was signed by the Governor on August 11. This bill will take effect 120 days after its enactment.

See also, Collaborative Drug Therapy Management (A.9715 Glick / S.7435 LaValle), described below in Professions category.

Professions

Licensure of Foreign Dental Faculty (A.8660 Glick / S.7183 Golden): This bill would extend the statutory exemption that allows full-time foreign-trained faculty at academic dental centers to receive a restricted dental license, which enables them to provide clinical services within schools' dental clinics. Currently, this law is set to expire on February 1, 2015. This bill would allow the academic dental centers to remain competitive employers by offering foreign faculty the opportunity to continue their medical practice. This is especially important given the current shortage of dental faculty in New York State. This bill was signed by the Governor on July 22. This bill took effect immediately.

Restricted Clinical Laboratory Licenses (A.9517-A Gottfried / S7199-A Hannon): This bill would allow the State Education Department (SED) to expand the scope of the clinical laboratory restricted license to include the study of mass spectroscopy and proteomics for restricted licensees employed at a federally designated cancer center. Previously, these fields were included under a limited license that is set to expire on September 1, 2016. This bill was signed by the Governor on August 11. This bill took effect immediately.

Collaborative Drug Therapy Management (A.9715 Glick / S.7435 LaValle): This bill would extend the collaborative drug therapy management pilot program for an additional year, which would give the Legislature time to examine the findings of SED's report on the efficacy and benefits of CDTM prior to adopting a more permanent solution. CDTM allows pharmacists to work with other health care practitioners to better manage patient care and improve health outcomes. Under the current statute, the program expired on September 14, 2014. This bill was signed by the Governor on July 22. This bill took effect immediately.

Continuing Education for Mental Health Practitioners (Chapter 15 of the Laws of 2014; A.8228-B DenDekker / S.6300 LaValle): This law makes technical changes to Chapter 486 of 2013, which requires mandatory continuing education for mental health counselors, marriage and family therapists, psychoanalysts, and creative arts therapists licensed in New York. The 2013 law is scheduled to go into effect on January 1, 2017. These amendments allow SED to enter into the rule-making process immediately in order to enable the 2013 law to become effective as planned on January 1, 2017. This law was signed by the Governor on March 17, 2014, and took effect on that date.

Social Services

Written Comments in Child Fatality Reports (A.9702 Lupardo / S.7667 Felder): This bill would make amendments to the statutory process for developing child fatality reports by requiring the inclusion of input and written comment from local social services districts referenced in the report. This bill has passed both houses, but has not yet been sent to the Governor. This bill would take effect immediately.

Medical Treatment for Destitute Children (A.9732 Lupardo / S.6813 Felder): This bill would authorize a local social services Commissioner or health Commissioner to give effective consent for medical, dental, health, and hospital services for any destitute child placed in foster care. The amendment would ensure the adequate provision of care to destitute children. This bill was signed by the Governor on August 11. This bill took effect immediately.

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In the New York State Agencies

By Francis J. Serbaroli

School Immunization Requirements

Notice of Adoption. The Department of Health amended subpart 66-1 of Title 10 NYCRR to amend and update NYS school entry immunization requirements. Filing date: February 2, 2014. Effective date: July 1, 2014. *See* N.Y. Register February 19, 2014.

Reduction to Statewide Base Price

Notice of Adoption. The Department of Health amended section 86-1.16 of Title 10 NYCRR to continue a reduction to the statewide base price for inpatient services. Filing date: February 4, 2014. Effective date: February 19, 2014. *See* N.Y. Register February 19, 2014.

Statewide Pricing Methodology for Nursing Homes

Notice of Adoption. The Department of Health added section 86-2.40 to Title 10 NYCRR to establish a new Medicaid reimbursement methodology for Nursing Homes. Filing date: February 3, 2014. Effective date: February 19, 2014. *See* N.Y. Register February 19, 2014.

Empire Clinical Research Investigator Program (ECRIP)

Notice of Adoption. The Department of Health added section 86-1.46 to Title 10 NYCRR to ensure that the redesigned ECRIP will continue individual physician research awards and provide larger center awards to teaching hospitals. Filing date: February 4, 2014. Effective date: February 19, 2014. *See* N.Y. Register February 19, 2014.

Capital Projects for Federally Qualified Health Centers (FQHCs)

Notice of Adoption. The Department of Health amended section 86-4.16 of Title 10 NYCRR to state that Capital Projects with a total

budget of less than $3 million shall be exempt from Certificate of Need (CON) requirements. Filing date: February 4, 2014. Effective date: February 19, 2014. *See* N.Y. Register February 19, 2014.

Episodic Pricing for Certified Home Health Agencies (CHHAs)

Notice of Adoption. The Department of Health amended section 86-1.44 of Title 10 NYCRR to exempt services to a special needs population from the episodic payment system for CHHAs. Filing date: February 4, 2014. Effective date: February 19, 2014. *See* N.Y. Register February 19, 2014.

Assisted Living Residences (ALRs) and Adult Care Facilities (ACFs)

Notice of Adoption. The Department of Health amended sections 487.4 and 488.4 of Title 18 NYCRR and section 1001.7 of Title 10 NYCRR to simplify the pre-admission and annual resident medical evaluation process for ALRs and ACFs. Filing date: February 3, 2014. Effective date: February 19, 2014. *See* N.Y. Register February 19, 2014.

Repeal of 14 NYCRR Part 1034

Notice of Repeal. The Office of Alcoholism and Substance Abuse Services repealed Part 1034 of Title 14 NYCRR to remove an outdated regulation. *See* N.Y. Register February 26, 2014.

Physician Assistants and Specialist Assistants

Notice of Withdrawal. The Department of Health withdrew its notice of proposed rulemaking published in the State Register on August 14, 2013 following receipt of a public comment letter. *See* N.Y. Register February 26, 2014.

Physician Assistants and Specialist Assistants

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 94 of Title 10 NYCRR to allow LPAs to prescribe controlled substances (including Schedule II) to patients under the care of the supervising physician. *See* N.Y. Register February 26, 2014.

Organ Transplant Provisions

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 405.13 and 405.22, and adding sections 405.30 and 405.31 to 10 NYCRR to update and add new provisions regarding organ transplant. *See* N.Y. Register February 26, 2014.

Administration of Vitamin K to Newborn Infants

Notice of Adoption. The Department of Health amended section 12.3 of Title 10 NYCRR to require Vitamin K administration to newborn infants to be consistent w/2012 American Academy of Pediatrics' Policy Statement. Filing date: February 25, 2014. Effective date: May 26, 2014. *See* N.Y. Register March 12, 2014.

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

Notice of Adoption. The Office of Mental Health amended Part 577 of Title 14 NYCRR to remove the 2014 trend factor for article 31 private psychiatric hospitals effective January 1, 2014. Filing date: March 4, 2014. Effective date: March 19, 2014. *See* N.Y. Register March 19, 2014.

Definition of Pediatric Severe Sepsis Update

Notice of Adoption. The Department of Health amended section 405.4 of Title 10 NYCRR to update pediatric severe sepsis definition to be consistent with generally accepted medical standards and to reflect current practice. Filing date: March 11, 2014. Effective date: March 26, 2014. *See* N.Y. Register March 26, 2014.

Hospital Indigent Care Pool Payment Methodology

Notice of Adoption. The Department of Health added section 86-1.47 to Title 10 NYCRR to establish the methodology for indigent care pool payments to general hospitals for the 3 year period 1/1/13 through 12/31/15. Filing date: March 11, 2014. Effective date: March 26, 2014. *See* N.Y. Register March 26, 2014.

Advance Directives

Notice of Adoption. The Department of Health amended section 400.21, and repealed of sections 405.43 and 700.5 of Title 10 NYCRR to establish a decision making process to allow competent adults to appoint an agent to decide about health care treatment. Filing date: March 11, 2014. Effective date: March 26, 2014. *See* N.Y. Register March 26, 2014.

Updates to SSI Offset and SNAP Benefit Offset

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 671.7 and 686.17 of Title 14 NYCRR to adjust reimbursement to affected providers for rent and food costs. Filing date: March 11, 2014. Effective date: March 26, 2014. *See* N.Y. Register March 26, 2014.

Mental Health Services—General Provisions

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 501 of Title 14 NYCRR to provide clarification with respect to outdated references within Title 14 NYCRR for providers of mental health services. *See* N.Y. Register April 9, 2014.

Presumptive Eligibility for Family Planning Benefit Program

Notice of Adoption. The Department of Health amended section 360-3.7 of Title 18 NYCRR to set criteria for the Presumptive Eligibility for Family Planning Benefit Program. Filing date: April 8, 2014. Effective date: April 23, 2014. *See* N.Y. Register April 23, 2014.

Expand Medicaid Coverage of Enteral Formula

Notice of Adoption. The Department of Health amended section 505.5 of Title 18 NYCRR to expand Medicaid coverage of enteral formula for individuals with HIV infection, AIDS or HIV-related illness or other diseases. Filing date: April 15, 2014. Effective date: April 30, 2014. *See* N.Y. Register April 30, 2014.

Medicaid Managed Care Programs

Notice of Adoption. The Department of Health repealed Subparts 360-10 and 360-11, sections 300.12 and 360-6.7, and added new Subpart 360-10 to Title 18 NYCRR to repeal old and outdated regulations and to consolidate all managed care regulations to make them consistent with statute Filing date: April 22, 2014. Effective date: May 7, 2014. *See* N.Y. Register May 7, 2014.

Restraint and Seclusion

Notice of Adoption. The Office of Mental Health amended Parts 27, 526 and 587 of Title 14 NYCRR to update regulations governing use of restraint and seclusion in facilities operated or licensed by the Office of Mental Health. Filing date: May 14, 2014. Effective date: June 4, 2014. *See* N.Y. Register June 4, 2014.

Prevention of Influenza Transmission

Notice of Adoption. The Office of Mental Health added Part 509 to Title 14 NYCRR to require unvaccinated personnel to wear surgical masks in certain OMH-licensed or operated psychiatric centers during flu season. Filing date: May 15, 2014. Effective date: June 4, 2014. *See* N.Y. Register June 4, 2014.

Adult Day Health Care Programs and Managed Long Term Care

Notice of Revised Rulemaking. The Department of Health revised its amendment of Part 425 of Title 10 NYCRR to create a hybrid model of adult day health care. *See* N.Y. Register June 11, 2014.

Statewide Planning and Research Cooperative System (SPARCS)

Notice of Revised Rulemaking. The Department of Health amended section 400.18 of Title 10 NYCRR to delete obsolete language, realign to current practice, and add new provisions, including mandated outpatient clinic data collection. *See* N.Y. Register June 11, 2014.

Hearing Aids

Notice of Adoption. The Department of Health amended section 505.31(h) of Title 18 NYCRR to streamline electronic billing and establish maximum reimbursable amounts based on an average products cost for hearing aids. Filing date: June 3, 2014. Effective date: June 18, 2014. *See* N.Y. Register June 18, 2014.

NYS Medical Indemnity Fund

Notice of Adoption. The Department of Health amended Subpart 69-10 to Title 10 NYCRR to provide the structure within which the NYS Medical Indemnity Fund will operate. Filing date: June 3, 2014. Effective date: June 18, 2014. *See* N.Y. Register June 18, 2014.

Rate Rationalization-Community Residences (CRs)/ Individualized Residential Alternatives (IRAs) Habilitation and Day Habilitation

Notice of Adoption. The Department of Health added Subpart 86-10 to Title 10 NYCRR to establish new rate methodology effective July 1, 2014. Filing date: June 10, 2014. Ef-

fective date: July 1, 2014. *See* N.Y. Register June 25, 2014.

Rate Rationalization—Intermediate Care Facilities for Persons with Developmental Disabilities (ICF/DDs)

Notice of Adoption. The Department of Health added Subpart 86-11 to Title 10 NYCRR to establish new rate methodology effective July 1, 2014. Filing date: June 10, 2014. Effective date: July 1, 2014. *See* N.Y. Register June 25, 2014.

Pathway to Employment Service

Notice of Adoption. The Department of Health amended Subparts 635-10, 635-99 and section 686.99 of Title 14 NYCRR to establish Pathway to Employment as a new HCBS waiver service. Filing date: June 10, 2014. Effective date: July 1, 2014. *See* N.Y. Register June 25, 2014.

Credentialing of Addictions Professionals

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 853, and added new Part 853 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 17, 2014. Effective date: June 17, 2014. *See* N.Y. Register July 2, 2014.

Criminal History Information Reviews

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services added Part 805 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 17, 2014. Effective date: June 17, 2014. *See* N.Y. Register July 2, 2014.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 815, and added new Part 815 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 17, 2014. Effective date: June 17, 2014. *See* N.Y. Register July 2, 2014.

Incident Reporting in OASAS Certified, Licensed, Funded or Operated Programs

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836, and added new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 17, 2014. Effective date: June 17, 2014. *See* N.Y. Register July 2, 2014.

Establishment, Incorporation and Certification of Providers of Substance Use Disorder Services

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 810, and added new Part 810 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 17, 2014. Effective date: June 17, 2014. *See* N.Y. Register July 2, 2014.

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

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA services. Filing date: June 12, 2014. Effective date: June 12, 2014. *See* N.Y. Register July 2, 2014.

Rate Setting for Non-State Providers: ICF/DD

Notice of Adoption. The Office for People With Developmental Disabilities added Subpart 641-2 to Title 14 NYCRR to establish a new rate methodology effective July 1, 2014. Filing date: June 17, 2014. Effective date: July 2, 2014. *See* N.Y. Register July 2, 2014.

Rate Setting for Non-State Providers: IRA/CR Residential Habilitation and Day Habilitation

Notice of Adoption. The Office for People With Developmental Disabilities added Subpart 641-1 to Title 14 NYCRR to establish a new rate methodology effective July 1, 2014. Filing date: June 17, 2014. Effective date: July 2, 2014. *See* N.Y. Register July 2, 2014.

Applications for Certification of Need

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending section 620.7(a) of Title 14 NYCRR to change requirements concerning the method of submission of CON applications. *See* N.Y. Register July 2, 2014.

Children's Camps

Notice of Emergency Rulemaking. The Department of Health amended Subpart 7-2 of Title 10 NYCRR to include camps for children with developmental disabilities as a type of facility with in the oversight of the Justice Center. Filing date: June 18, 2014. Effective date: June 18, 2014. *See* N.Y. Register July 9, 2014.

Standards for Adult Homes and Adult Care Facilities Standards for Enriched Housing

Notice of Emergency Rulemaking. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR to revise Parts 487 and 488 in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: June 20, 2014. Effective date: June 20, 2014. *See* N.Y. Register July 9, 2014.

Service Intensity Weights (SIWs) and Average Length-of-Stay (ALOS), Administrative Appeals and Out-of-State Providers

Notice of Adoption. The Department of Health amended Subpart 86-1 of Title 10 NYCRR to delay the rebasing of the acute hospital inpa-

tient rates and implementation of the service intensity weights for 2014. Filing date: June 20, 2014. Effective date: July 9, 2014. *See* N.Y. Register July 9, 2014.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office of Mental Health repealed Part 524 and amended Parts 501 and 550 of Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: June 18, 2014. Effective date: July 18, 2014. *See* N.Y. Register July 9, 2014.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended Parts 624, 633 and 687, and added Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD system. Filing date: June 19, 2014. Effective date: June 22, 2014. *See* N.Y. Register July 9, 2014.

Rate Rationalization—Intermediate Care Facilities for Persons with Developmental Disabilities

Notice of Emergency/Proposed Rulemaking. The Department of Mental Health amended Subpart 86-11 of Title 10 NYCRR to amend the new rate methodology effective July 1, 2014. Filing date: July 1, 2014. Effective date: July 1, 2014. *See* N.Y. Register July 16, 2014.

Rate Rationalization for Community Residences/ Individualized Residential Alternatives Habilitation and Day Habilitation

Notice of Emergency/ Proposed Rulemaking. The Department of Health amended Subpart 86-10 of Title 10 NYCRR to amend the new rate methodology effective July 1, 2014. Filing date: July 1, 2014. Effective date: July 1, 2014. *See* N.Y. Register July 16, 2014.

Immediate Needs for Personal Care Services

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 360-3.7 and 505.14 of Title 18 NYCRR to provide for meeting the immediate needs of Medicaid applicants and recipients for personal care services. *See* N.Y. Register July 16, 2014.

Rate Setting for Non-State Providers—IRA/CR Residential Habilitation and Day Habilitation

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities added Part 641 to Title 14 NYCRR to establish a new rate methodology effective July 1, 2014. Filing date: July 1, 2014. Effective date: July 1, 2014. *See* N.Y. Register July 16, 2014.

Rate Setting for Non-State Providers—ICF/DD Facilities

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities added Subpart 641-2 to Title 14 NYCRR to establish a new rate methodology effective July 1, 2014. Filing date: July 1, 2014. Effective date: July 1, 2014. *See* N.Y. Register July 16, 2014.

Amendments to Rate Setting for Non-State Providers: IRA/CR Residential Habilitation and Day Habilitation

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended Subpart 641-1 of Title 14 NYCRR to amend the new rate methodology effective July 2014. Filing date: July 1, 2014. Effective date: July 2, 2014. *See* N.Y. Register July 16, 2014.

Supervised IRA/CR Residential Habilitation Unit of Service Change

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended 635-10.5(b) and 671.7 of Title 14 NYCRR to conform existing OPWDD regulations to the change in the unit of service from monthly to daily. Filing date: July 1, 2014. Effective date: July 1, 2014. *See* N.Y. Register July 16, 2014.

Pathway to Employment Fee Adjustment

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended Subparts 635-10, 635-99 and section 686.99 of Title 14 NYCRR to increase fees for Region 3 and make other changes to requirements for the pathway to employment service. Filing date: July 1, 2014. Effective date: July 2, 2014. *See* N.Y. Register July 16, 2014.

Amendments to Rate Setting for Non-State Providers: ICF/DD

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended Subpart 641-2 of Title 14 NYCRR to amend the new rate methodology effective July 2014. Filing date: July 1, 2014. Effective date: July 2, 2014. *See* N.Y. Register July 16, 2014.

Implementation of a Program for the Designation of Vital Access Providers

Notice of Proposed Rulemaking. The Office of Alcoholism and Substance Abuse Services proposed amending Part 802 to Title 14 NYCRR to ensure preservation of access to essential services in economically challenged regions of the state. *See* N.Y. Register July 23, 2014.

State Aid for Public Health Services: Counties and Cities

Notice of Proposed Rulemaking. The Department of Health proposed

repealing Parts 39 and 40; and adding new Part 40 to Title 10 NYCRR to modernize certain regulations, including standards of performance for eligible public health services. *See* N.Y. Register July 23, 2014.

Amendment of Certificate of Need (CON) Applications

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 600.3 and 710.5 of Title 10 NYCRR to eliminate requirement for Public Health & Health Planning Council review of certain types of amendments to CON applications. *See* N.Y. Register July 23, 2014.

Mental Health Services—General Provisions

Notice of Adoption. The Office of Mental Health amended Part 501 of Title 14 NYCRR to provide clarification with respect to outdated references within Title 14 NYCRR for providers of mental health services. Filing date: July 7, 2014. Effective date: July 23, 2014. *See* N.Y. Register July 23, 2014.

HCBS Waiver Community Habilitation Services

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending sections 635-10.1, 635-10.4(b)(4) and 635-10.5 of Title 14 NYCRR to make revisions to HCBS Waiver Community Habilitation services. *See* N.Y. Register July 23, 2014.

Opioid Overdose Prevention Programs

Notice of Adoption. The Department of Health amended section 80.138 of Title 10 NYCRR to establish standards for approval of any opioid overdose prevention programs. Filing date: July 15, 2014. Effective date: July 30, 2014. *See* N.Y. Register July 30, 2014.

Prevention of Influenza Transmission by Health Care and Residential Facility and Agency Personnel

Notice of Proposed Rulemaking. The Department of Health proposed amending section 2.59 of Title 10 NYCRR to clarify regulatory amendments and implement more flexible reporting provisions. *See* N.Y. Register July 30, 2014.

Medical Assistance Payment for Outpatient Programs and COPS

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health amended Part 588; and repealed Part 592 of Title 14 NYCRR to amend Part 588 by increasing Medicaid fees to OMH-licensed day treatment programs for children and repeal and outdated rule. Filing date: July 15, 2014. Effective date: July 15, 2014. *See* N.Y. Register July 30, 2014.

Disclosure of Confidential Cancer Information

Notice of Adoption. The Department of Health amended section 1.31 of Title 10 NYCRR to allow more types of relevant research access to the Registry, expand use of confidential data to surveillance and evaluation. Filing date: July 22, 2014. Effective date: August 6, 2014. *See* N.Y. Register August 6, 2014.

Outpatient Services Licensed Under the Mental Hygiene Law

Notice of Proposed Rulemaking. The Department of Health proposed adding Subpart 86-12 to Title 10 NYCRR to create methodology for adjusting provider reimbursement in OPWDD, OHM & OASAS certified clinics based on annual patient visits. *See* N.Y. Register August 6, 2014.

Update Increase Percentage for Leases

Notice of Adoption. The Office for People With Developmental Disabilities amended section 635-6.3 of Title 14 NYCRR to adjust reimbursement to affected providers for lease costs. Filing date: July 22, 2014. Effective date: August 6, 2014. *See* N.Y. Register August 6, 2014.

Blood Banks

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 58-2 of Title 10 NYCRR to update practice standards, reflect changes and provide clarification of regulation provisions for blood banks and transfusion services. *See* N.Y. Register August 13, 2014.

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

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

Tejet Express Transportation, Inc. (DOH administrative hearing decision dated June 9, 2014, Denise Lepicier, Administrative Law Judge). Two audits were conducted by the OMIG to verify the accuracy of ambulette driver license numbers on Medicaid claims between January 1, 2008 and December 31, 2011 and to verify drivers' compliance with the Vehicle and Traffic Law license requirements for claims between June 1, 2011 and December 31, 2011. The Administrative Law Judge upheld the audit findings that two of the drivers used were not qualified to drive an ambulette and that the provider did not properly include the drivers' license numbers on all claims filed.

St. Barnabas Hospital (DOH administrative hearing decision dated May 23 2014, Denise Lepicier, Administrative Law Judge). The Administrative Law Judge held that the request by the hospital for a hearing to contest OMIG audit adjustments was untimely. The State is not bound by the representations made by an OMIG auditor to the attorney for the hospital that the time to submit a request for a hearing was tolled during settlement discussions, as the regulations and the Final Audit Report provided a 60-day time limit. Errors of a State employee cannot bind the State.

Ali John Jazayeri, D.D.S. (DOH administrative hearing decision dated April 3, 2014, Denise Lepicier, Administrative Law Judge). The Administrative Law Judge upheld the Medicaid repayment obligation of a dentist who had billed Medicaid directly as fee-for-service for patients who were covered for dentistry under their Medicaid managed care plan, of which the dentist had been aware.

New York State Attorney General Press Releases

Compiled by Joseph A. Murphy and Karen S. Southwick

Medicaid Fraud Investigation at Brooklyn Adult Day Health Care Facility Leads to Four Arrests, $6.5 Million Settlement and Shutdown of Facility—August 12, 2014—Four employees of an adult day health care program in Brooklyn were arrested and the facility shut down after a Medicaid fraud investigation. Undercover visits by a healthy senior revealed that a registered nurse and another medical employee at the facility falsified medical admissions forms to ensure he qualified for services that he was too healthy to receive. Further investigation uncovered that the facility hired unqualified individuals to provide social work services, perform initial psycho-social assessments and diagnose the emotional and mental needs of registrants. The operator of the Brooklyn facility agreed to pay $6.5 million to resolve the Attorney General's civil claims. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-four-arrests-and-65-million-settlement-medicaid-fraud.

Rochester Healthcare Worker Pleads Guilty to Striking A 90-Year-Old Nursing Home Patient Suffering From Dementia—August 12, 2014—A certified nursing assistant at a nursing home in Rochester pled guilty to misdemeanor harassment for hitting a 90-year-old female patient suffering from dementia. The slap reportedly was loud and left a red mark on the resident's forehead. Sentencing has been scheduled for January 12, 2015. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-rochester-healthcare-worker-striking-90-year-old.

Woman Arrested for Allegedly Impersonating a Licensed Practical Nurse at a Far Rockaway Nursing Home—August 7, 2014—A Brooklyn woman was arrested for allegedly masquerading as a licensed practical nurse at a nursing home in Far Rockaway, Queens. The defendant never obtained a license in New York State and faces Grand Larceny charges and up to 15 years in prison for taking $90,000 in salary over the 18 months that she was not qualified. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-woman-allegedly-impersonating-licensed-practical.

Pfizer Settles Allegations of Deceptive Advertising Practices and Off-label Promotion of Immunosuppressive Drug Rapamune—August 6, 2014—Pfizer entered a $35 million settlement with the New York Attorney General and 40 other state Attorneys General and the District of Columbia arising from alleged improper marketing and promotion of the immunosuppressive drug Rapamune. Pfizer subsidiary Wyeth Pharmaceuticals Inc. allegedly improperly promoted Rapamune (1) for liver, heart and lung transplants when the drug was approved only for use after kidney transplants; (2) for conversion use (switching a patient from another drug to Rapamune), which was also unapproved; and (3) in unapproved drug combinations. The complaint further alleges that Pfizer misrepresented Rapamune's uses and benefits through an orchestrated campaign of promotional talks by Wyeth-retained doctors, misleading presentations of data, and funding of studies at hospitals and transplant

centers designed to encourage off-label uses of Rapamune. The settlement prohibits Pfizer from, among other things, making, or causing to be made, any written or oral claim that is false, misleading, or deceptive regarding any Pfizer product. New York's share of the settlement is over $1.7 million. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-pfizer-end-deceptive-advertising-practices-and.

Brooklyn Medical Center Enters Into Settlement Agreement For False Billings to The New York State Medicaid Program—July 30, 2014—Brooklyn Plaza Medical Center entered into a $600,000 settlement agreement to resolve allegations that the diagnostic and treatment center ran a satellite facility, the Whitman Ingersoll Farragut Health Center, without an operating certificate. The settlement also resolves allegations that Brooklyn Plaza Medical Center disguised the satellite facility's Medicaid billings to make them appear as if the services were rendered at the Brooklyn Plaza Medical Center, not the satellite center. Those fraudulent billings caused the Medicaid program to offer inflated reimbursements for services rendered. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-brooklyn-medical-center-ran-satellite-facility.

Medication Technician Arrested for Stealing Prescription Narcotics from Elderly Residents of Assisted Living Facility for Personal Use—July 25, 2014—A medication technician formerly employed by an assisted living facility in Pittsford was arrested, facing 17 charges for allegedly stealing a total of 650 narcotic pills for personal use from eight patients ranging in age from 66 to 98 years old. The technician allegedly substituted non-narcotic medications that were not prescribed for the patients in question. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-medication-technician-allegedly-stealing-prescription.

Westchester County Medical Transportation Company and Owner Arrested for Allegedly Falsifying Transportation Requests to Inflate Reimbursement—July 10, 2014—The owner of a Westchester County medical transportation company was arrested on felony charges for allegedly stealing more than $200,000 from the Medicaid program. The corporation and the owner are charged with top counts of Second Degree Grand Larceny for allegedly altering transportation requests sent to them by medical facilities authorizing taxi pick-ups and drop-offs for Medicaid patients. The corporation and owner are charged with doctoring the requests during a four-year period to claim requests for ambulette service, which is paid by Medicaid at a rate four times higher than for taxis. http://www.ag.ny.gov/press-release/westchester-medical-transport-company-owner-arrested-felony-theft-charges-medicaid.

EmblemHealth Agrees to Overhaul Its Claims Review Process As Part of Settlement—July 9, 2014—New York City-based EmblemHealth, Inc., entered into a settlement, requiring the health insurer to reform its behavioral health claims review process, cover residential treatment and charge the lower, primary care co-payment for outpatient visits to mental health and substance abuse treatment providers. The settlement also requires the health insurance plan to submit previously denied mental health and substance abuse treatment claims for independent review. The review could result in more than $31 million being returned to members wrongfully denied benefits. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-emblem-health-wrongly-denying-mental-health-and.

Lawsuit Alleges False Claims Act Violations Against Continuum Health Partners, Beth Israel Medical Center, and St. Luke's Roosevelt for Failure to Return Funding—June 27, 2014—New York-based Continuum Health Partners, Inc., Beth Israel Medical Center, and St. Luke's-Roosevelt Hospital Center are being sued for failing to return money to the New York State Medicaid Program. The complaint in intervention alleges that between 2009 and 2010, Beth Israel and St. Luke's-Roosevelt submitted improper claims to Medicaid for services rendered to Healthfirst enrollees as a result of a computer error. The complaint also alleges that in February of 2011, Continuum, which at the time of the alleged conduct operated Beth Israel and St. Luke's-Roosevelt identified over 900 potentially improper claims to Medicaid, totaling approximately $1,000,000. The complaint alleges that despite learning of alleged improper claims, Continuum failed to take steps to repay all of the affected claims within the allowed time period. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-lawsuit-against-continuum-health-partners-beth-israel.

Buffalo Man Sentenced for Fraudulently Operating as an Optometrist and Providing Ophthalmic Dispensing Services Without a License—June 23, 2014—A Tonawanda man was sentenced on charges related to fraudulently operating as an optometrist and providing ophthalmic dispensing services without a license for either profession. The individual had obtained more than $15,000 from the State of New York/Excellus Medicaid Managed Care. The individual has made full restitution in the amount of $116,821 and completed the required 150 hours of community service prior to sentencing. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-buffalo-man-who-collected-over-100000-operating.

Westchester Nurse and Nurse Aide Arrested for Failing to Provide Care and for Making False Statements—June 23, 2014—A licensed practical nurse and a certified nurse aide were arrested on charges they failed to provide proper care to an 84-year-old resident of the New York State Veterans' Home at Montrose and for making false statements in the resident's medical records to falsely reflect that they had provided the care. The victim was a Korean War veteran who suffered from dementia

and Parkinson's disease. He was found on the floor of his room and pronounced dead shortly thereafter. An investigation revealed that the nurse and nurse aide failed to properly check on him during the night. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-westchester-nurse-and-nurse-aide-failure-provide-care.

Nurse Charged With Failure to Give Life-Saving Care—June 5, 2014—A registered and supervising nurse at a Kingston nursing home failed to follow the wishes of an 80-year-old resident and the directive of the nursing home by failing to administer CPR when the resident stopped breathing. During an internal investigation, the nurse provided a false written statement in which she claimed that she was not in the room when the resident stopped breathing and was told about the incident after it happened. http://www.ag.ny.gov/press-release/kingston-nurse-charged-failure-give-life-saving-care-nursing-home-resident.

Nine Employees of Medford Nursing Home Arrested in Ongoing Criminal Negligence Case in Connection with Death of Resident—June 5, 2014—Nine employees, including the facility's top administrator, were indicted in Suffolk County in connection with the death of a 72-year-old resident who was at the nursing home for then-temporary rehabilitation. The corporation operating the home was indicted on charges of attempting to cover up the circumstances surrounding the 2012 death. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-nine-suffolk-county-nursing-home-employees.

GlaxoSmithKline, LLC Enters Settlement to End Deceptive Advertising Claims—June 4, 2014—GlaxoSmithKline, LLC (GSK) entered into a $105 million settlement with the New York State Attorney General and 43 other State Attorneys General and the District of Columbia arising from alleged improper marketing and promotion of the asthma drug Advair and the anti-depressant drugs Paxil and Wellbutrin. New York's share of the settlement is over $4.1 million. The complaint alleges that GSK engaged in deceptive and misleading practices when it marketed Advair, Paxil, and Wellbutrin for off-label uses and concealed risks associated with Paxil. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-glaxosmithkline-end-deceptive-advertising.

Broome County Nurse Arrested for Endangering Nursing Home Resident and Falsifying Records After Resident Fall—May 28, 2014—A Licensed Practical Nurse was arraigned for failing to follow nursing home policy after a resident fell and injured himself. She was charged with Falsifying Business Records in the First Degree, Endangering the Welfare of an Incompetent or Physically Disabled Person in the Second Degree, and Willful Violation of Health Laws, in the Town of Union Justice Court, Broome County. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-broome-county-nurse-arrested-endangering-nursing-home.

Group and Creator of Group Enter Into Settlement Due to Lapse in Group Health Insurance—May 22, 2014—A group created to give members of the local arts community access to affordable group health insurance and its creator entered into a $30,000 settlement in connection with a lapse in group health insurance coverage due to the creator's failure to pay premiums despite repeated notices from the health insurance carrier. The creator used the administrative fees for his own expenses, resulting in the insolvency of the group. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-30000-settlement-group-allowed-members-health-insurance.

Medical Doctor Convicted for Aiding and Abetting Two Unlicensed Individuals to Perform Plastic Surgery—May 8, 2014—A licensed physician in New York and Connecticut was convicted for allowing two unlicensed individuals to perform plastic surgery on unsuspecting patients. The physician aided and abetted the two individuals in performing cosmetic surgeries on women without general anesthesia, leaving them permanently disfigured as a result. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-conviction-medical-doctor-who-allowed-fake-plastic-surgeons.

Pharmacy Owner Sentenced in Medicaid Scheme—May 5, 2014—A pharmacy owner was sentenced to a 1-to-3-year prison term for his part in a multi-year scheme that cost the state Medicaid program $16 million. The owner pled guilty to felony Enterprise Corruption and is one of six individuals arrested by the Attorney General's Medicaid Fraud Control Unit in a scheme that involved more than a dozen pharmacies. The scheme involved paying HIV patients to refrain from filling their HIV prescriptions and then billing Medicaid for those unfilled prescriptions. The owner has agreed to pay $500,000 in civil forfeiture. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-prison-term-rogue-pharmacy-owner-16-million-medicaid-theft.

Seventeen Nursing Home Employees Charged with Neglecting Resident—April 25, 2014—A variety of felony and misdemeanor charges were filed against 17 employees. The charges stem from an investigation showing a pattern of neglect of a resident. The resident suffered from Huntington's chorea, a neurological disease that left the resident completely non-ambulatory and bedridden. Video footage showed nurses and certified nurse's aides routinely ignored their duties regarding the resident and his documented needs. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-charges-filed-against-17-nursing-home-employees-neglecting.

Aide Charged With Endangering Quadriplegic Suffolk County Nursing Home Resident Dropped On Floor— April 11, 2014—A certified nurse's

aide in Suffolk County was arrested and charged with endangering and neglecting a 57-year-old quadriplegic nursing home resident. The patient suffered an approximately five-inch long laceration to the head, a fractured knee and bruising to her heel and buttocks area after the aide allegedly attempted to move her from a wheelchair to a bed using a mechanical lift, but without seeking help in the transfer. The patient's care plan specifically required two staff members to move the resident. The aide then also failed to get help for her injured patient. If convicted, the aide faces up to 4 years in prison on the two felony and one misdemeanor charges. http://www.ag.ny.gov/press-release/aide-charged-endangering-suffolk-county-nursing-home-resident.

Former Nursing Home Nurse Pleads Guilty to Neglecting Elderly Resident for Withholding Medication From Blind 73-Year-Old Resident with Alzheimer's—April 1, 2014—A licensed practical nurse formerly employed by a nursing home in Fishkill admitted to a misdemeanor charge of Willful Violation of the Health Laws for failing to administer a prescribed medication to a 73-year-old resident who suffers from Alzheimer's disease. Because of difficulty swallowing as a result of advanced dementia, the resident was to have received a hypertension medication and protein supplement through a gastronomy tube. As part of the plea agreement, the former nurse surrendered his nursing license and was sentenced to 100 hours of community service and a $1,000 fine. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-former-nursing-home-nurse-neglecting-elderly.

Former Nursing Home Business Manager Sentenced for Theft of $18,000 in Residents' Funds—March 27, 2014—A former Massena nursing home business manager who admitted to stealing $18,000 in resident funds was sentenced to three years' probation, which will include counseling for gambling problems. The defendant pled guilty to petit larceny for diverting funds in 2011 and 2012 by making false entries into the facility's books and forging names on receipts. After the nursing home detected and reported the crime, the manager repaid more than $10,000 of the $18,000 that was stolen, and the nursing home reimbursed patients for the remainder. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-business-manager-theft-nursing-home-residents%E2%80%99.

Ten Nursing Home Employees Charged with Neglecting Disabled Resident After Hidden Camera Mistreatment of Double-Leg Amputee—March 25, 2014—Criminal charges were filed against six nurses and four nursing assistants at a nursing and rehabilitation center in Rochester who allegedly neglected a double amputee suffering from partial paralysis and other ailments. The Attorney General's office used a hidden camera to investigate at the request of the resident's son, who had become suspicious that his father was being mistreated. The video allegedly revealed that the employees failed to dispense prescription medications, measure blood sugar and blood pressure levels, properly care for the resident's catheter and neglected the resident's incontinence care and prescribed range of motion exercises. The resident also was reported to have been left to lay immobile in his bed for hours at a time, with no hands-on care during the aides' entire shifts. The nurses and aides allegedly falsified documents in an effort to conceal their neglect. They were charged with a variety of felonies and misdemeanors. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-charges-against-10-nursing-home-employees-neglecting.

Health Care Center Nurse's Aide Arrested for Neglect Resulting In Patient's Broken Leg—March 21, 2014—A nurse's aide at a health care center in Utica has pled not guilty to multiple charges stemming from an alleged incident of neglect in June 2013 involving a 95-year-old resident. The aide allegedly attempted to move the resident herself despite the patient's care plan requiring two people to assist with a lift. The resident slipped and was lowered to the floor. The aide did not report the incident, and two days later it was determined that the resident had two fractures in her lower right leg. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-heritage-health-care-center-nurse%E2%80%99s-aide-neglect.

Health Insurer Settles with Attorney General in Investigation of Wrongly Denied Mental Health Benefits, Will Overhaul Behavioral Health Claims Review Process, Pay Past Claims and $300,000 Penalty—March 20, 2014—A health insurer has agreed to a settlement with the Attorney General's Office concerning compliance with New York's mental health parity law. Timothy's Law, enacted in New York in 2006, requires that insurers provide mental health coverage at least equal to coverage provided for other health conditions. An investigation by the Attorney General's Health Care Bureau found that since 2009, when it outsourced administration of behavioral health benefits to ValueOptions, a managed behavioral health organization, the insurer denied 39% of its members' claims for inpatient psychiatric treatment and 47% of its members' claims for inpatient substance abuse treatment, rates that are more than double the plan's denial rate for inpatient medical claims.

The settlement requires the health insurer to comply with mental health laws by reforming its behavioral health claims review process, covering residential treatment and charging lower primary care co-payments for outpatient visits to most mental health and substance abuse treatment providers. The settlement also requires the health insurance plan to submit previously denied mental health and substance abuse treatment claims for independent review, which could result in more than $6 million being returned to its members.

Under the settlement, the insurer agreed to cover residential treatment for behavioral health conditions, including eating and substance abuse disorders, and has designated $1.5 million for reimbursement of members' past residential treatment claims that had previously not been covered. More than 3,000 members may be eligible for reimbursement for denied claims, including for residential treatment. The insurer will also submit to monitoring and will pay $300,000 to the OAG as a civil penalty. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-health-insurer-wrongly-denied-mental-health.

Former Assistant Manager of Disability Services Center Pleads Guilty to Stealing Money from Disabled Residents—March 17, 2014—A former assistant manager at a center for individuals with disabilities in Schoharie pled guilty to a misdemeanor charge of falsifying business records for stealing $1,503 from disabled residents. The former assistant manager, who used the funds to purchase cell phones, calling cards, and iTunes gift cards for herself, will pay restitution and will appear on a Medicaid exclusion list. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-former-assistant-manager-disability-services.

Pharmacist and Pharmacy Owners Charged with Felonies for Illegal Prescription Buybacks from HIV Patients and Fraudulently Billing Medicaid—March 11, 2014—The Supervising Pharmacist and two owners of a Bronx pharmacy were arrested for allegedly buying back prescriptions and billing Medicaid as if the medications had been dispensed. The defendants allegedly paid patients hundreds of dollars in cash in exchange for forgoing their prescriptions, most of which were for HIV medication. They also allegedly paid Medicaid recipients cash for referring new patients and funneled proceeds through several companies they owned and controlled. The Attorney General obtained a court order freezing the bank accounts held by the defendants for more than $9.8 million, the amount the pharmacy obtained from Medicaid in less than a year. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-pharmacy-owners-and-pharmacist-operating-illegal

Dentist Who Lied About Past Conviction in South Carolina While Seeking to Renew Dental License in New York State Sentenced to One-to-Three Years in Prison—March 11, 2014—A dentist convicted of a felony for lying about a past conviction while seeking a dental license in New York State was sentenced to one-to-three years in prison. The dentist was previously convicted in South Carolina for unlawfully distributing Vicodin, resulting in his dental license being revoked in that state. Failure to disclose this conviction on an application to renew his New York State dental license resulted in the felony charges and the surrender of his license to practice dentistry in the State of New York. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-dentist-who-lied-about-past-conviction.

Albany Nurse's Aide Sentenced for Twisting Elderly Patient's Arm, Fracturing Bone—March 10, 2014—A certified nurse's aide at a rehabilitation and nursing center in Albany pled guilty to a felony charge of physical endangerment for fracturing the arm of an elderly nursing home patient. The aide twisted the patient's arm after the resident became combative and struck her in the face. The aide was sentenced to 30 days in the Albany County Jail and five years' probation and will surrender her certified nurse's aide certificate. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-sentencing-albany-elder-abuse-case.

Long-Term Pharmacy Omnicare Resolves Allegations of Kickbacks Given by Pharma Giant Amgen with $4.2 Million Settlement—February 28, 2014—Long-term-care pharmacy Omnicare has agreed to pay $4.2 million to settle allegations that it demanded kickbacks in the form of price concessions from drug manufacturer Amgen to switch the pharmacies' long-term care patients suffering from chronic kidney disease, among other ailments, to a drug manufactured by Amgen. Under the agreement, the New York Medicaid Program will be reimbursed $664,137.09. Amgen and Omnicare allegedly conspired to switch patients in long-term care facilities, such as nursing homes, to the nephrology drug Aranesp by giving discounts, market share rebates, speaker fees and other price concessions to Omnicare in exchange for influencing Omnicare's selection and utilization of Aranesp. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-42m-settlement-kentucky-based-long-term-pharmacy-omnicare.

NY Radiology Practice Settles Allegations of Kickback, False Billing for Billing Medicaid and Medicare for Unnecessary Tests—February 25, 2014—New York, New Jersey and the United States have entered into a $15.5 million settlement agreement with a Long Island radiology practice to resolve allegations of kickbacks and the submission of false claims to the Medicaid and Medicare programs for diagnostic outpatient imaging services not ordered by a treating physician and not medically necessary. New York's Medicaid recovery will be $2,915,217.

Between 1999 to 2010, more than 40,000 false claims were submitted to the New York Medicaid program from the radiology practice for various imaging services. The radiology practice allegedly submitted false claims for nuclear stress tests that were fraudulent because the radiology practice had service agreements with the referring physicians under which the physicians were paid more than fair market value for supervision of the tests. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-155m-settlement-ny-radiology-practice-billed-medicaid-and.

Endo Pharmaceuticals Agrees to $173 Million Settlement To Resolve Off-Label Marketing Allegations— February 21, 2014—New York has joined with other states and the federal government in a $173 million global settlement with pharmaceutical manufacturer Endo Pharmaceuticals to resolve civil allegations of unlawfully marketing the drug Lidoderm for conditions not approved by the Food and Drug Administration.

According to the qui tam, or whistleblower lawsuit, Endo unlawfully marketed Lidoderm for use in connection with lower back pain or chronic pain, whereas the FDA approved Lidoderm only for the treatment of pain associated with post-herpetic neuralgia, or shingles. Endo will pay $172,916,967 to the states and federal government, pay criminal penalties and forfeitures of almost $21 million, and enter into a Deferred Prosecution Agreement with federal authorities. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-173m-settlement-pharmaceutical-giant-resolve-label-marketing.

Generic Pharmaceutical Manufacturers Enter Into Settlement Agreement Resolving Allegations of Anticompetitive Arrangement— February 19, 2014—Generic Pharmaceutical Manufacturers Ranbaxy Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. entered into a Settlement Agreement resolving allegations that they had a collusive agreement, under which each of the generic drug companies committed not to challenge certain "first to file" regulatory exclusivities held by the other and to protect each party's market positions with respect to dozens of drugs. The settlement with the Attorney General requires the parties to terminate the "no challenge" agreement, refrain from entering into similar agreements in the future, and make monetary payments to New York State totaling $300,000. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-generic-pharmaceutical-companies-entering.

New York State Office of the Medicaid Inspector General Update

Compiled by Jamie Dughi Hogenkamp

Chemical Dependence Service Provider Guidance Published—July 30, 2014—http://www.omig.ny.gov/latest-news/795-chemical-dependence-guidance.

Nassau Doctor Denied Medicaid Reinstatement—June 30, 2014—http://www.omig.ny.gov/latest-news/793-shaffer.

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Guidance on Compliance Element Six Released—May 6, 2014—http://www.omig.ny.gov/latest-news/781-compliance-guidance-six.

Expired Drugs, Filthy Conditions at Pharmacy Net Medicaid Enrollment Denial—April 17, 2014—http://www.omig.ny.gov/latest-news/769-ana-pharmacy.

Updates to the Consumer Portal—April 16, 2014—http://www.omig.ny.gov/latest-news/768-updates-to-the-consumer-portal.

NYS Medicaid Inspector General Releases Fiscal Year 2014-15 Work Plan—April 2, 2014—http://www.omig.ny.gov/latest-news/764-2014-15-work-plan.

Three Items Added to OMIG Compliance Library: Best Practices, Enhancements, Insufficiencies—March 31, 2014—http://www.omig.ny.gov/latest-news/778-three-items-added-to-compliance-library; http://www.omig.ny.gov/compliance.

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The Editor would like to thank Hiscock & Barclay's Summer Associate and Albany Law School Student Jamie Dughi Hogenkamp for her assistance with this edition.

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For Your Information

By Claudia O. Torrey

In the Spring 2014 edition of the Health Law Section's *Journal*, this author noted the evolving area of "connected health." As a nod to the topic, the following three items may be of interest:

- On August 26, 2014, Kevin Counihan became the Marketplace CEO for HealthCare.gov; Mr. Counihan comes to this position after serving as the CEO of Connecticut's successful state-based health insurance exchange.[1] As he oversees the operations of HealthCare.gov, duties for Counihan will also include managing relationships with state exchanges and shepherding the upcoming November 15, 2014 open enrollment period of the Affordable Care Act.
- The National Institute of Standards & Technology ("NIST") has issued its first draft of guidelines intended to help federal agencies balance the benefits and the risks of third party mobile applications ("apps"). The draft guidelines,[2] entitled *Technical Considerations for Vetting 3rd Party Mobile Applications*, had a public comment period through September 18, 2014.

  According to the guidelines' abstract, "[t]oday's commercially available mobile devices are handheld computing platforms with wireless capabilities, geographic localization, cameras, and microphones… the purpose of this document is to provide guidance for vetting 3rd party software apps for mobile devices."
- "Word on the street"—The Apple Company is rumored to be in the process of developing a wearable iWatch, which will encompass a health metrics sensor.[3] An argument could be made for the proposition that "large tech companies have an interest in health that goes beyond…creating cool devices that consumers would use for recreational purposes."[4] Indeed, as of September 9, 2014, the "iWatch" became known as Apple Watch; the big wearable wave is coming in 2015![5]

Endnotes

1. http://www.informationweek.com.
2. NIST Special Publication 800-163 (Draft) (August 2014).
3. Parmar, Arundhati, *Apple is Talking With Top Insurers Too And Not Just FDA*, http://www.mddionline.com (August 22, 2014).
4. *Id.*
5. See Haston Stewart, "The Big Wearable Wave is Coming in 2015," www.mobilegeeks.com/the-big-wearable-wave-is-coming-2015-wt-ceo-christian-stammel (October 14, 2014).

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The Nonprofit Revitalization Act of 2013

By Mark Thomas

Background

New York's Nonprofit Revitalization Act of 2013 passed both houses of the state legislature late in the 2013 session and was approved by Governor Cuomo in January 2014. Many provisions apply to all nonprofits and call for the development and implementation of specific corporate policies and procedures. The bulk of the law, which went into effect on July 1, 2014, and its key provisions are summarized in this article.

The Revitalization Act, the first significant overhaul of the Not-for-Profit Corporation Law (NFPCL) since its inception in 1970, makes several changes to streamline processes that will benefit all nonprofits and their counsel. For example, under the old law, if a nonprofit wanted to dispose of substantially all its assets, it needed the approval of the Attorney General and a Justice of the Supreme Court. As of July 1, the approval of either, not both, is sufficient. Under the old law, nonprofits were categorized into four partially overlapping groups: Types A, B, C and D. As of July 1, there are two types: "charitable" and "non-charitable."

Definitions

Key terms have been added to or changed in the law. It is important to understand these definitions because they partially shape the reach and impact of all the substantive requirements in the act. These include:

- An **affiliate** is any entity controlled by, in control of or under common control with a nonprofit corporation.
- **Charitable purposes** are corporate purposes that are charitable, educational, religious, scientific, literary, cultural or for the prevention of cruelty to children or animals.
- The definition of **key employee** now matches the Internal Revenue Code (*i.e.*, a director, officer or employee who has "substantial influence" over the finances and operation of a nonprofit).
- **Related party** is an individual, or a relative of an individual, who is a director, officer or key employee of the nonprofit or an affiliate or an entity in which the individual or relative has a 35 percent or greater ownership interest, or 5 percent or greater if it is a professional corporation or partnership.
- **Related-party transaction** is any transaction, agreement or other arrangement in which a related party has a financial interest and in which the nonprofit corporation, or any affiliate, participates.
- The law includes several other important new definitions for the role of **an independent director**. Under this section, *all* of the following criteria must be satisfied. The independent director:
  - Is not and has not been an employee of the nonprofit corporation or an affiliate within the past three years and does not have a relative who is or was a "key employee" of the corporation or affiliate in the past three years;
  - Has not received from the corporation or an affiliate, and does not have a relative who has received, more than $10,000 in direct compensation in the prior three years (expense reimbursement is not considered compensation);
  - Is not a current employee of, nor has a substantial financial interest in, nor has a relative who is an officer of, nor has a substantial financial interest in, an entity that in any of the prior three years has made payments to or received payments of $25,000 or more from the nonprofit corporation or an affiliate. Charitable contributions are not considered payments.

Note that the independent director status is *only* relevant to the audit oversight requirement. In other words, whether a director is "independent" has no bearing on the director's role on the board except that he or she cannot serve on the audit committee.

Compensation

The previous NFPCL simply stated that a corporation must pay compensation "in reasonable amounts" to directors, officers and members for services rendered.

The new law includes additional detail. It provides that no person who may benefit from the compensation may be present at or in any way participate in any board or committee deliberation or vote regarding the compensation. The board or committee may request that the individual provide background information or answer questions at a meeting prior to commencement of the board's or committee's deliberations.

Audit Oversight

The new audit oversight provisions are effective January 1, 2015, for any corporations with annual revenue of less than $10 million in the last fiscal year ending prior to January 1, 2014.

All nonprofits that file independent audit reports to the Attorney General's Charities Bureau (*i.e.*, charities and

entities that solicit funds from the general public or the state) are subject to paragraph 1 below:

> 1. The board or a committee comprised solely of [*sic*] independent directors must oversee the accounting and financial reporting processes of the corporation and the audit of the corporation's financial statements. The board or the committee must annually retain an independent auditor to conduct an audit and, at the conclusion of the audit, review the results and management letter with the auditor.

Nonprofits that file independent audit reports to the Attorney General's Charities Bureau *and* that have annual revenue of $1 million or more *also* are subject to paragraphs 2 and 3 below:

> 2. The board or committee must review the scope and planning of the audit with the independent auditor prior to the commencement of the audit. The board or committee must review and discuss with the independent auditor any identified material risks and weaknesses in internal controls; any restrictions on the scope of the audit or access to information; any significant disagreements between the auditor and management; and the adequacy of the corporation's accounting and financial reporting processes. The board or committee must annually consider the performance and independence of the auditor.
>
> If the above duties are performed by a committee, it must report its activities to the board.
>
> 3. The board or audit committee must oversee the adoption, implementation of, and compliance with the conflict of interest and whistleblower policies described later in this article.
>
> If the board or committee is that of a corporation that controls other corporations, the duties described in this section may be carried out by the board or committee on behalf of any such controlled corporations. This provision applies to all applicable charities, whether above or below the $1 million threshold stated above.

Related-party Transactions

The new law includes a first-ever provision for related parties. In the new law, no related party may participate in the deliberation or vote but may be requested to provide information regarding a related-party transaction prior to the board's or a committee's deliberation. Before entering into a related-party transaction, the corporation's board or a committee must determine that it is fair, reasonable and in the corporation's best interest. Any director, officer or key employee with an interest in a related-party transaction must disclose to the board or committee the material facts of the interest.

In addition, the board or committee must:

- Consider alternatives that may be available;
- Approve the transaction by a majority of those present;
- Contemporaneously document the reasons for the approval and consideration of alternatives, if any.

The certificate of incorporation or bylaws may include additional safeguards regarding related-party transactions.

The Attorney General (AG) may bring a legal action to void or rescind a related-party transaction if the transaction violates the law, was unreasonable or was not in the best interests of the corporation. The AG is empowered to request that a court allow the AG to:

- Seek restitution to the corporation;
- Remove directors and officers;
- Require that the enriched party pay back any profits;
- Require an individual to compensate for or replace the corporation's property or assets used or sold in the transaction;
- In the case of conduct that was willful and intentional, seek payment to the corporation of double the benefit received by any related party.

Conflicts of Interest

Another new feature of the law includes the requirement that every nonprofit adopt a conflict-of-interest policy. Note that the law does not define what constitutes a conflict of interest, but rather leaves it to each entity to craft its own. The law requires that, at a minimum, a conflict of interest policy must include:

- A definition of what constitutes a conflict of interest;
- Procedures for disclosing a conflict to the audit committee or the board;
- A requirement that the interested individual not be present at or participate in any board or committee deliberations or vote on a matter or transaction in which the interested individual is conflicted;

- A provision that prohibits the interested individual from attempting to "influence improperly" any deliberation or vote;
- Documentation of the existence and resolution of the conflict, including any meeting minutes;
- Procedures for disclosing, addressing and documenting related-party transactions.

Prior to appointment to the board and annually thereafter, every director must complete and provide to the corporation's secretary a statement disclosing, to the best of the director's knowledge, the following:

- Any entity of which the individual is a director, officer, employee or owner that has "a relationship" with the corporation;
- Any transaction involving the corporation and in which the individual "might" have a conflicting interest.

The secretary must provide copies of all statements to the chair of the audit committee or chair of the board.

If the corporation has adopted and implemented a conflict of interest policy pursuant to another federal, state or local law that is "substantially consistent" with this law, it will be deemed in compliance with this law. The new law does not require a corporation to adopt any specific conflict of interest policy nor does it supersede or limit the requirements of any other law or rule regarding conflicts of interest.

Whistleblower Policy

The Nonprofit Revitalization Act added a new section requiring the adoption and implementation of a whistleblower policy by every nonprofit having 20 or more employees *and* more than $1 million annual revenue.

The policy shall require that no director, officer, employee or volunteer shall suffer intimidation, harassment, discrimination or other retaliatory action, including adverse employment consequences, for good faith reporting of any action or suspected action taken by or within the corporation that is illegal, fraudulent or in violation of any corporate policy.

A whistleblower policy must include all of the following:

- Procedures for reporting violations or suspected violations of law or corporate policy;
- A procedure for preserving the confidentiality of whistleblower reports;
- Designation of a director, officer or employee to administer the policy and report to the audit committee or the board.

A copy of the policy must be distributed to all directors, officers, employees and volunteers who provide "substantial services" to the corporation.

If the corporation has adopted and implemented a whistleblower policy pursuant to another federal, state or local law that is "substantially consistent" with this law, it will be deemed in compliance with this law. The new law does not supersede or limit the requirements of any other law or rule regarding whistleblower policies or protections.

The Revitalization Act is a significant milestone that furthers corporate transparency and accountability. While many of its provisions have been considered recommended best practices, they now have the force of law. Further, the Attorney General is empowered to take remedial action for noncompliance. The Revitalization Act is also consistent with the IRS's evolving perspective that nonprofit and charitable governance practices must be consistent with those applicable to stock companies subject to the federal Sarbanes-Oxley Act.

All nonprofits are advised to embrace the spirit and letter of the Revitalization Act by examining and, as necessary, modifying corporate documents and governance practices with guidance from experienced and trusted professionals. As community resources, nonprofits and their governing bodies owe special duties to the communities they serve.

Mark Thomas is General Counsel to the Healthcare Association of New York State (HANYS).

Medical Marijuana Legislation in New York State

By Erin McGrath

On July 5, 2014, Governor Andrew Cuomo signed the Compassionate Care Act into law, and New York State became the twenty-third state to legalize medical marijuana. This new law was the result of a three-way agreement between the Executive, the Assembly, and the Senate, and allows health care practitioners in New York State to recommend medical marijuana to patients with serious illnesses[1] in a non-smokeable form. The law provides that the medical marijuana infrastructure will be completed by January 7, 2016, unless the Commissioner and the Superintendent of Police believe that the law cannot be implemented at that time without compromising public health and safety interests, and the law will sunset on July 7, 2021.

Under the law, patients may receive medical marijuana if a health care practitioner determines that "the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical use of marijuana for the serious condition." Once a health care practitioner makes this determination, he or she must issue a "certification" in order for the patient to receive medical marijuana from a registered organization. A "certification," rather than a prescription, must be used in order to avoid conflict with federal law, which labels marijuana a Schedule 1 controlled substance, thereby prohibiting its use for either medical or recreational purposes.

Patients are allowed to possess a 30-day supply of medical marijuana, and caregivers may possess a 30-day supply per patient (limited to five patients). That supply must be the in the form that was recommended by the certifying health care practitioner and be kept in the original package with all labeling intact. When patients use the medical marijuana allotted to them, they cannot consume the medical marijuana in a public place and must have their registry identification card in their immediate possession. If it is necessary, patients may consume their dosage using drug paraphernalia that would otherwise be prohibited under the General Business Law.

In order to purchase medical marijuana from a registered organization, patients and their caregivers, if designated, must register with the Department and receive a registry identification card. The patient or the caregiver will then present the registry identification to the registered organization at the time of purchase to show that he or she has been properly certified to receive medical marijuana. In addition to examining the registration identification card, the registered organization must also (i) consult I-STOP; (ii) ensure all dispensations comply with any recommendations or limitations; (iii) provide a safety insert; and (iv) provide a receipt. A copy of the receipt and the customer's registry ID must be kept by the registered organization for six years, and the registered organization must transmit these records to the Department immediately upon sale.

"Under the law, patients may receive medical marijuana if a health care practitioner determines that 'the patient is likely to receive therapeutic or palliative benefit from the primary or adjunctive treatment with medical use of marijuana for the serious condition.'"

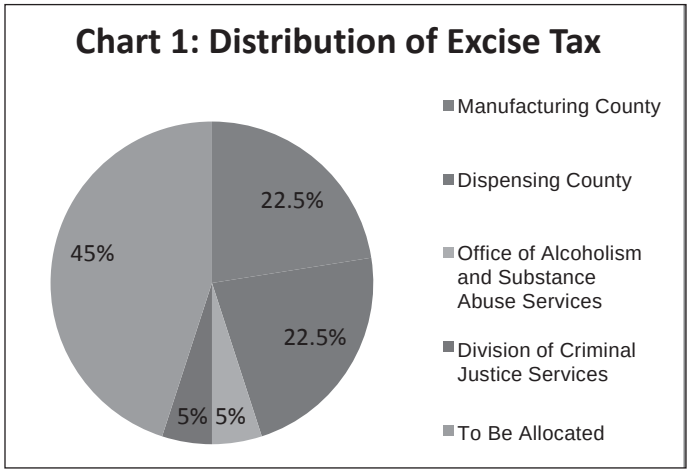
Initially, it is expected that most purchases will be made in cash, as many banks do not allow transactions from dispensaries on the debit or credit cards they issue, citing the Bank Secrecy Act (BSA), as well as the official rules of Visa, Discover, Master Card, and American Express, which forbid the use of their cards for purchasing illegal goods or services. Banking laws and the credit card official rules could pose a problem for registered organizations as well, as many banks have also refused to open checking and savings accounts or provide loans to organizations that cultivate or buy and sell medical and recreational marijuana.

Registered organizations will be "seed to sale" for-profit or nonprofit entities that are responsible for all activities related to medical marijuana cultivation and sale, including purchasing seeds, cultivation, harvest, internal and external clinical quality control, manufacture, packaging, sale, delivery, transport, and distribution of medical marijuana. Each of these activities must take place in indoor, enclosed, and secure facilities, which are subject to additional restrictions as determined by the Commissioner.

In response to concerns that legalization will allow for the proliferation of illegal marijuana use in New York State, the statute also contains provisions regarding the criminal diversion of medical marijuana, which do not apply to health care practitioners, registered organizations, or persons who act in good faith. Criminal diversion of medical marijuana in the first degree is a class E felony, and occurs when a health care practitioner provides a certification when he or she has reasonable grounds to know that: (i) the recipient has no medical need for medical marijuana; or (ii) the patient is seeking medical marijuana for purposes other than the treatment of a serious illness. Criminal diversion of medical mari-

juana in the second degree is a class B misdemeanor, and is when a person sells, trades, delivers, or otherwise provides medical marijuana to another person with reasonable grounds to know that he or she is not an individual who is registered to receive medical marijuana.

The new law also creates a 7% excise tax on all medical marijuana sold in New York State, which cannot be added on as a separate charge or line item. The excise taxes imposed on each registered organization will be determined from the filing of monthly returns to the Commissioner, and payment will be due to the Commissioner with that return on or before the twentieth of each month.



The taxes collected will be deposited into a special revenue fund known as the New York State Medical Marijuana Trust Fund. A portion of the funds will go the State, the municipality where the medical marijuana was grown, and the municipality where it was sold (see Chart 1). For the municipalities, the funds from the excise tax will be allocated in proportion to the gross sales originating from dispensation or manufacture of medical marijuana in each county.

Endnote

1. Cancer, HIV or AIDS, amyotrophic lateral sclerosis, Parkinson's disease, multiple sclerosis, damage to the nervous tissue of the spinal cord with intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, clinically associated symptoms or a complication of the diseases listed above or their treatments, including: Cachexia or wasting syndrome; severe or chronic pain; severe nausea; seizures; and severe or persistent muscle spasms. The Commissioner will also determine whether to add treatment of Alzheimer's, muscular dystrophy, dystonia, post-traumatic stress disorder, and rheumatoid arthritis by January 7, 2016.

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Mental Health Parity: Trends Emerging in New York

By Ashley B. Antler and Ronald G. Blum

A recent surge of activity in New York, which comes on the heels of related federal activity, indicates that mental health parity is on the radar of state legislators, officials and regulators. In November 2013, the federal government released long-awaited final regulations clarifying requirements to ensure parity between mental health and substance use disorder benefits and medical/surgical benefits. Beginning in 2014, the federal parity requirements were extended to the individual and small group insurance markets, significantly broadening their reach. In the months following issuance of final federal parity rules and extension of the parity requirements to a broader population, New York legislators have taken steps to expand state law protections in line with federal law and state officials and regulators have taken actions to more vigorously enforce federal and state parity laws.

State action in the wake of the final federal regulations is not entirely unexpected. Guidance issued by the federal government in connection with the final parity rules makes clear that states have primary authority to enforce the federal mental health parity laws.[1] Increased attention to parity compliance makes sense in light of the expansion of parity requirements to a broader population. Recent parity developments in New York are notable because of their breadth, involving a diverse range of stakeholders, and because they have occurred within a short time after the issuance of final federal regulations, signaling that at least one state has renewed its focus on this area of the law.[2]

This article discusses the confluence of legal developments in New York State regarding mental health parity in the months following issuance of final federal parity regulations, and highlights some key, emerging trends: a focus on coverage of residential treatment and increased scrutiny of processes to determine medical necessity of mental health and substance use benefits.

Federal and New York State Mental Health Parity Laws

The Mental Health Parity and Addiction Equity Act of 2008

The federal mental health parity statute, the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (commonly referred to as "MHPAEA"),[3] is intended to ensure "parity," or equality between mental health and substance use disorder benefits and medical/surgical benefits offered by health plans. It prohibits group health plans and health insurance issuers that provide mental health and substance use disorder benefits from imposing more stringent limitations on these benefits than on corresponding medical/surgical benefits.

MHPAEA augments prior federal parity protections in several ways. It extends parity requirements to substance use disorders and mandates that financial requirements (such as copayments, deductibles and coinsurance) and treatment limitations (including limits on the scope or duration of treatment) applicable to mental health and substance use disorder benefits be no more restrictive than the predominant limits applicable to substantially all medical/surgical benefits. MHPAEA prohibits separate cost-sharing requirements or treatment limitations and requires a health plan to provide benefits for out-of-network mental health and substance use disorders if it provides out-of-network medical/surgical benefits.

"Guidance issued by the federal government in connection with the final parity rules makes clear that states have primary authority to enforce the federal mental health parity laws."

It also requires making available the criteria for medical necessity determinations and reasons for denial of mental health and substance use disorder benefits, upon request.[4] MHPAEA does not require that group health plans and health insurance issuers cover mental health and substance use disorder benefits. Instead, MHPAEA requires that, if provided, these benefits must be "on par" with medical/surgical benefits.

MHPAEA applies to large group health plans and issuers offering large group health insurance. The Affordable Care Act ("ACA")[5] and its implementing regulations extend MHPAEA's requirements to the individual and small group insurance markets, with limited exceptions, broadening the reach of these protections to an estimated 62 million Americans.[6]

Federal Regulations

In February 2010, the Departments of the Treasury, Labor and Health and Human Services—the federal agencies with joint responsibilities for enforcing and providing guidance about the parity laws—published interim final regulations outlining requirements under MHPAEA, which applied to group health plans and group health insurance issuers for plan years beginning on or after July 1, 2010.[7]

In November 2013, these Departments issued final regulations clarifying protections under MHPAEA and the interim rules, which became effective for plan years beginning on or after July 1, 2014.[8] The final regulations generally track the interim rules, but clarify requirements in several areas, including "intermediate levels of care," such as residential treatment and so-called "nonquantitative treatment limitations."

The federal regulations set forth requirements concerning nonquantitative treatment limitations, such as medical management standards limiting or excluding benefits based on medical necessity or appropriateness. The regulations preclude a group health plan from imposing a nonquantitative treatment limitation on mental health and substance use disorder benefits unless, under the terms of the plan, as written and in operation, the processes, strategies, evidentiary standards, or other factors used in applying the limitation to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, those used in applying the limitation to medical/surgical benefits in the same benefit classification.[9] The final regulations eliminate the exception permitted under the interim rules, allowing for differential application of such limitations to mental health and substance use disorder and medical/surgical benefits based on clinically appropriate standards of care.[10]

New York State Mental Health Parity Law

New York's mental health parity law, known as "Timothy's Law," was passed in 2006[11] and requires "broad-based coverage for the diagnosis and treatment of mental, nervous or emotional disorders or ailments… at least equal to coverage provided for other health conditions."[12] New York law also requires coverage of the diagnosis and treatment of substance use disorders.[13] These requirements contrast with federal parity law, which does not require coverage of mental health and substance use disorder benefits.[14] Because Timothy's Law requires large group health plans that provide medical and surgical benefits to also include mental health benefits, the law triggers application of the federal parity law requirements to ensure that mental health and substance use disorder benefits are on par with medical/surgical benefits.

Recent Surge of Parity Developments in New York

Following the issuance of final federal parity regulations and the broadened applicability of federal parity requirements under the ACA, New York legislators, officials and regulators have increased their focus on parity. In recent months, a confluence of parity-related developments has led to new legislation, enforcement actions against insurers and issuance of updated state guidance regarding plans' obligations under parity law.

Legislative Developments

In June 2014, New York State enacted legislation related to insurance coverage for patients suffering from substance use disorders.[15] This statute (a) strengthens existing substance use disorder coverage mandates and aligns such coverage with federal mental health parity requirements; (b) enhances utilization review ("UR") requirements concerning qualifications of clinical reviewers, clinical review criteria and the speed of decisions, as well as coverage while decisions are pending; (c) clarifies regulatory enforcement obligations with respect to these reforms; and (d) creates a substance use disorder workgroup to study and make recommendations.

The recent legislation requires every policy that provides hospital, medical, major medical or similar comprehensive or comprehensive-type coverage to provide inpatient and outpatient coverage for substance use disorder diagnosis and treatment, including detoxification and rehabilitation services, and expressly requires that coverage be consistent with requirements under MHPAEA.[16] The new law incorporates the federal requirement that coverage for substance use disorder diagnosis and treatment not apply financial requirements or treatment limitations to inpatient or outpatient substance use disorder benefits that are more restrictive than the predominant financial requirements and treatment limitations applied to substantially all medical/surgical benefits.[17] The legislation also establishes heightened obligations applicable to UR decisions concerning substance use disorder treatment, including requirements regarding individuals eligible to act as clinical peer reviewers, clinical review criteria to be used, applicable time frames for making determinations and continued coverage of substance use disorder treatment while determinations are pending.[18]

Attorney General Enforcement

The New York State Office of the Attorney General has also assumed an active role in the state's mental health parity enforcement.[19] The Attorney General's Office has indicated that it is "vigorously enforcing" mental health parity laws and that ensuring adequate access to mental health and substance use disorder treatment should be a priority for the state.[20] In the first half of 2014, the Attorney General's Office entered into agreements with three insurance companies concerning compliance with these laws.[21]

Two of these investigations focused on insurance coverage of mental health and substance use disorder treatment at residential treatment facilities. In particular, the Attorney General has required insurance companies to cover medically necessary treatment at residential treatment facilities, and provide reimbursement in the event an individual incurred costs for, but was denied coverage of, residential treatment services.

The enforcement actions also demonstrate the Attorney General's scrutiny of the processes employed to determine medical necessity of mental health and substance use disorder benefits. Although guidance issued in connection with the final federal regulations makes clear that in assessing whether a nonquantitative treatment limitation, such as a medical necessity determination procedure, complies with parity requirements, "[d]isparate results alone do not mean that the [nonquantitative treatment limitations] in use do not comply with these requirements,"[22] the Attorney General's office has compared denial rates of mental health and substance use disorder services to medical/surgical services. The recent Attorney General agreements establish detailed requirements concerning UR procedures and allow for potential reimbursement of expenses incurred as a result of claims denied on medical necessity grounds.

These enforcement actions make clear that insurers in New York State should closely scrutinize compliance with parity requirements, and in particular, the comparability of UR processes employed with respect to mental health and substance use disorder benefits, on the one hand, and medical/surgical benefits, on the other. These actions also highlight regulators' increasing interest in intermediate levels of care, including residential treatment, and signal that plans should review their benefits in this area.

Regulatory Guidance

In the same month that the new substance use disorder legislation was enacted, New York State's Department of Financial Services ("DFS"), the state agency with oversight of insurance companies that do business in New York, issued a Circular Letter on the impact of MHPAEA, the MHPAEA final regulations and the ACA on mental health and substance use disorder benefits in New York's health insurance market.[23] This Circular Letter replaces agency guidance from 2009 and 2010.

Notably, the Circular Letter highlights federal guidance regarding intermediate levels of care, including residential treatment, and explains application of the federal rules to this benefit.

Federal guidance issued in connection with the final regulations clarifies treatment of "intermediate levels of care," such as residential treatment, within the six benefit classifications identified in the federal rules. The preamble to the final rule makes clear that although MHPAEA does not create a "benefit mandate," requiring greater mental health and substance use disorder benefits than medical/surgical benefits, plans and issuers may not exclude intermediate levels of care from parity requirements by claiming that these benefits do not fall within one of the six benefit classifications under the federal rules. Plans and issuers must assign intermediate mental health and substance use disorder benefits to the six classifications in the same way that they assign intermediate medical/surgical benefits. By way of example, the guidance explains that if a plan classifies care in a skilled nursing facility as inpatient care, it must treat care in a residential treatment facility for mental health and substance use disorders as inpatient care.[24]

According to DFS, care at residential treatment facilities should be classified as an inpatient benefit because care at skilled nursing facilities is treated as such.[25] As a result, DFS explains, any financial requirements or treatment limitations applicable to residential treatment facilities for mental health and substance use disorder conditions may not be more restrictive than the predominant financial requirements and treatment limitations applied to substantially all medical/surgical benefits in the inpatient classification. Furthermore, any processes, strategies, evidentiary standards, or other factors used in applying nonquantitative treatment limitations to mental health and substance use disorder benefits must be comparable to, and no more stringent than, those applicable to inpatient medical/surgical benefits.[26]

This DFS guidance underscores regulators' growing interest in intermediate levels of care. It remains to be seen whether regulators' interest leads to an increase in the number of intermediate care providers, or increased consumer demand for these services and insurance coverage of them.

Mental Health Parity Trends Emerging in New York

Focus on Residential Treatment

The final federal rules, the New York Attorney General's enforcement actions and the state regulatory guidance highlight coverage of intermediate levels of care—in particular, residential treatment—as a parity issue. Regulators in other states may turn their attention to residential treatment. It is not clear whether coverage of residential treatment will also be the focus of lawsuits. For example, a recent California class action alleged improper denial of residential treatment coverage in violation of federal parity laws.[27]

Moreover, in light of the ACA's mandate that mental health and substance use disorder benefits be included as one of ten essential health benefits, intermediate levels of care, such as residential treatment, are poised to garner more attention, perhaps as a more cost-effective alternative to inpatient treatment.

Increased Scrutiny of Utilization Review

The procedures underlying medical necessity determinations are another recent focus of federal regulations, state legislation and the New York Attorney General. The final parity regulations clarify requirements concerning a plan's disclosure of information relevant to an individual's claim for benefits, including documents concerning medical necessity criteria for both medical/surgical and

mental health and substance use disorder benefits and the processes and other factors used to apply a nonquantitative treatment limitation to such benefits.[28] Additionally, the state substance use disorder legislation mandates detailed UR requirements unique to the inpatient substance use disorder setting, including heightened requirements concerning clinical peer reviewers, clinical review criteria and expedited time frames for reviews. Close inspection of UR procedures to determine medical necessity is also reflected in the Attorney General's recent parity enforcement actions, which scrutinize UR procedures applicable to mental health and substance use disorder benefits, and establish remedies for aggrieved individuals and detailed requirements for the plans' UR processes moving forward.

"A diverse set of players in New York… are refocusing on mental health parity in the wake of final federal regulations. As a result, insurers are facing increased pressure to critically assess their compliance with parity requirements."

Looking Ahead

A diverse set of players in New York—legislators, regulators and the state's Attorney General—are refocusing on mental health parity in the wake of final federal regulations. As a result, insurers are facing increased pressure to critically assess their compliance with parity requirements. As consumers gain awareness of these protections, they may make additional demands on states and insurers alike to enforce these rights.[29]

Recent developments in New York may be harbingers of actions to come in other states. It remains to be seen whether mental health parity activity in other states will reflect the efforts of multiple legal actors, as has been the case in New York. Given the recent expansion of federal parity requirements to the individual and small group populations, it is reasonable to expect further developments in this area in New York and elsewhere.

Endnotes

1. Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (hereinafter, "Final Rules Under MHPAEA"), 78 Fed. Reg. 68240, 68252 (Nov. 13, 2013). Notwithstanding this, the federal Department of Health and Human Services has enforcement authority if a state is not enforcing the law. *Id.*
2. New York is not alone in focusing on this issue. For example, in April 2013, the Connecticut Insurance Department entered into an agreement with Anthem Health Plans, Inc., to readjust claims submitted by behavioral health providers that were impacted by changes in billing codes applicable to behavioral health services. Press Release, State of Conn. Ins. Dep't, "Insurance Commissioner: Anthem to Readjust Claims for Behavioral Health Providers" (Apr. 24, 2013). *See also* Accusation, *In the Matter of Kaiser Found. Health Plan*, Enforcement Matter No. 11-543 (Dep't of Managed Health Care of the State of Cal. Jun. 24, 2013) (Doc. No. 124055).
3. 29 U.S.C. § 1185a.
4. *Id.*
5. Pub. L. No. 111-148.
6. Under the ACA, as of January 1, 2014, all new, "non-grandfathered" small group and individual market plans are required to cover ten "essential health benefit" categories, which include mental health and substance use disorder benefits, and are required to do so at parity with medical/surgical benefits. The Department of Health and Human Services has estimated that the ACA's reforms extending MHPAEA requirements to the individual and small group markets and providing previously uninsured Americans access to health insurance coverage will extend the federal parity protections to an estimated 62 million Americans. Kirsten Beronio et al., Dep't of Health & Hum. Serv., Office of the Assistant Sec'y for Planning and Evaluation, ASPE Research Brief, "Affordable Care Act Expands Mental Health and Substance Use Disorder Benefits and Federal Parity Protections for 62 Million Americans" (Feb. 20, 2013), *available at* http://aspe.hhs.gov/health/reports/2013/mental/rb_mental.cfm.
7. Interim Final Rules Under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, 75 Fed. Reg. 5410 (Feb. 2, 2010).
8. Final Rules Under MHPAEA, *supra* note 1, at 68240.
9. 45 C.F.R. § 146.136(c)(4); 26 C.F.R. § 54.9812-1(c)(4); 29 C.F.R. § 2590.712(c)(4). The federal regulations establish six classifications of benefits (inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care; and prescription drugs) and require that mental health and substance use disorder benefits be provided in every classification in which medical/surgical benefits are offered.
10. Final Rules Under MHPAEA, *supra* note 1, at 682464-45.
11. Laws of New York, 2006, ch. 748; N.Y. Ins. Law §§ 3221(l)(5), 4303(g) & (h).
12. N.Y. Ins. Law §§ 3112(1)(5)(A) & 4303(g)(1). Timothy's Law sets forth minimum benefits coverage requirements for mental, nervous and emotional disorders and also requires heightened coverage for adults and children with "biologically based mental illness" (which include schizophrenia/psychotic disorders, major depression, bipolar disorder, delusional disorders, panic disorder, obsessive compulsive disorder, bulimia and anorexia) and children with "serious emotional disturbances." *Id.* §§ 3112(1)(5)(B)-(C) and 4303(g)(2)(A)-(B). However, under federal parity law, plans must go beyond these minimum requirements to the extent that such benefits are less generous than comparable medical/surgical benefits.
13. *Id.* §§ 3221(l)(6) and 4303(k).
14. However, as noted above, the ACA requires all new, "non-grandfathered" small group and individual market plans to cover mental health and substance use disorder benefits as one of ten essential health benefits, at parity with medical/surgical benefits. *See supra* note 6.
15. Assembly Bill No. 10164/Senate Bill No. 7912, codified as Chapter 41, Laws of New York, 2014.
16. *Id.* §§ 1-3.
17. *Id.*
18. *Id.* §§ 5-9.
19. Other states' Attorneys General have also focused their attention on access to mental health services. For example, the Massachusetts Attorney General has entered into agreements with several insurance carriers for failure to cover mental health services, and has written to America's Health Insurance Plans

("AHIP"), the trade association for health insurance carriers, urging compliance with mental health coverage requirements under Massachusetts' law. Letter from Martha Coakley, Attn'y Gen. of Mass., to Karen Ignagni, President and CEO, AHIP (May 2, 2013).

20. *See, e.g.*, Press Release, N.Y.S. Office of the Attn'y Gen., "A.G. Schneiderman Announces Settlement With Health Insurer That Wrongly Denied Mental Health Benefits to Thousands of New Yorkers" (Mar. 20, 2014).

21. *See* Press Release, N.Y.S. Office of the Attn'y Gen., "A.G. Schneiderman Announces Settlement With Health Care Insurer For Wrongfully Denying Mental Health Treatment Claims" (Jan. 15, 2014); Press Release, N.Y.S. Office of the Attn'y Gen., "A.G. Schneiderman Announces Settlement With Health Insurer That Wrongly Denied Mental Health Benefits to Thousands of New Yorkers" (Mar. 20, 2014); Press Release, N.Y.S. Office of the Attn'y Gen., "A.G. Schneiderman Announces Settlement with Emblem Health for Wrongly Denying Mental Health and Substance Abuse Treatment For Thousands of New York Members" (Jul. 9, 2014).

22. Final Rules Under MHPAEA, *supra* note 1, at 68245.

23. N.Y.S. Dep't of Fin. Serv., Ins. Circular Letter No. 5, "Impact of Mental Health Parity and Addiction Equity Act of 2008 ("MHPAEA"), Affordable Care Act ("ACA"), and the MHPAEA Final Rule on Mental Health and Substance Use Disorder Benefits in New York's Health Insurance Market" (hereinafter, "Ins. Circular Letter No. 5") (June 4, 2014).

24. Final Rules Under MHPAEA, *supra* note 1, at 68246.

25. New York State Dep't of Fin. Serv., Ins. Circular Letter No. 5, *supra* note 23, § II.B.8 (June 4, 2014).

26. *Id.*

27. *Wit v. UnitedHealthcare Ins. & United Behavioral Health*, No. 3:14-cv-02346 (N.D. Cal. May 21, 2014).

28. *See, e.g.*, 45 C.F.R. § 146.136(d). In issuing final regulations, the federal government expressed an interest in "transparency" regarding application of nonquantitative treatment limitations, and ensuring that individuals have necessary information to compare nonquantitative treatment limitations of medical/surgical benefits and mental health and substance use benefits, and to ensure that parity protections are provided. *See* Final Rules Under MHPAEA, *supra* note 1, at 68247-48.

29. To date, there have been a limited number of private lawsuits alleging parity violations. In October 2013, the Southern District of New York dismissed a class action suit against UnitedHealth Group and several of its subsidiaries for denial of mental health and substance use disorder benefits in violation of, *inter alia*, MHPAEA and the ACA. Decision and Order Granting Defendants' Motion to Dismiss and Denying Plaintiffs' Motion for Preliminary Injunction, *N.Y.S. Psychiatric Ass'n v. UnitedHealth Grp.*, Case No. 1:13-cv-01599 (S.D.N.Y. Oct. 31, 2013), ECF No. 102.

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Postpartum Sterilization: Underserved Women Struggle with Bureaucratic Laws and Regulations

By Cassandra E. Henderson, Lillian E. Ringel, Hasan Nezan, Shadi Rezai and Stuart Sherman

History

In the early 1900s, sterilizations (of men and women) were performed not only as a way of preventing pregnancy in women with life-threatening illnesses, but also as a way of implementing ideas espoused by eugenicists. These ideas included: preventing interracial couples, intellectually deficient people, and mentally ill people from procreating. As Justice Oliver Wendell Holmes, Jr. infamously wrote in *Buck v. Bell*, "[t]hree generations of imbeciles are enough."[1]

"[T]he [30-day prior consent] regulation as originally drafted is now an onerous bureaucratic barrier to effective, timely, practical, and affordable contraception for large groups of disenfranchised women."

By the 1970s, new sterilization techniques increased its use. In the United States, between 1970-1976, female sterilizations jumped from 192,000 per year to 674,000 per year.[2] This jump in numbers was due partially to the use of less invasive sterilization techniques, and was more insidiously due to continuing noxious thoughts about sterilizing the perceived "unfit." For example, the Relf sisters, ages 12 and 14, were sterilized as minors with neither their assent nor their mother's consent. Both were black, poor, and intellectually disabled. Their mother (who was illiterate) signed an "x" on a sheet of paper that allowed her two daughters to be sterilized (even though she believed she was signing her name so that her daughters could receive birth control). This story illustrates the effects that a confluence of race, socioeconomic status, literacy status, and disability status had on two minor girls because there were no governmental protections in place to regulate sterilizations paid for by government money. The sisters eventually brought suit,[3] which eventually led to the requirement that a patient seeking sterilization must give a doctor informed consent before the doctor can perform a sterilization procedure on that patient.

Present-Day Need for Less Stringent Consent Standards

Today, in the United States, postpartum sterilization by tubal ligation is a widely used, safe, and highly effective procedure. With few exceptions, this method of contraception requires the patient to complete a federally regulated informed consent form at least 30 days before sterilization is performed.[4] This consent documentation requirement has historic origins in abusive practices of the 20th century that were designed as a barrier to reproduction by disenfranchised women.[5]

However, as illustrated by the following cases, the regulation as originally drafted is now an onerous bureaucratic barrier to effective, timely, practical, and affordable contraception for large groups of disenfranchised women.

> **Case 1:** A 37-year-old woman with four children presents at a Bronx hospital with HIV, a low CD4 count, and is in pre-term labor ("PTL") at 33 weeks gestation. The patient requests a postpartum sterilization, saying that she had previously signed a consent form for the procedure at a Manhattan hospital. A call to that hospital found there was no record of a signed consent form, and she did not have a copy of the consent form herself. Doctors performed a caesarian section, but did not perform a bilateral tubal ligation ("BTL").
>
> **Case 2:** A 46-year-old woman with five children and a history of syphilis, hepatitis C, and abuse of multiple drugs presented at term in active labor requesting postpartum sterilization. During one of her three prenatal visits, she asked to attend and was subsequently referred to a sterilization class. However, at the time, she was not allowed to take the class because her pregnancy was not advanced enough. Subsequently, she missed several prenatal appointments and did not return until she was within 30 days of her due date, too close to her due-date to be eligible for postpartum sterilization.

We argue that for affected underserved women, this legislation results in an ethical violation of their rights to exercise the same degree of autonomy that their more economically and socially advantaged counterparts can exercise.[6]

In New York City, regardless of the payor, patients must complete an informed consent document at least 30

days prior to sterilization. However, unlike their underserved counterparts, wealthy women are not burdened to the same degree by the timing of the consent requirement.[7]

With New York's expansion of Medicaid coverage, more women will have the option of postpartum sterilization.[8] We suggest revising the consent requirement in order to address current social conditions of underserved women in a way that would support patient autonomy by retaining prudent informed consent requirements. Improved access to sterilization procedures is a means of reducing unintended pregnancy and the associated heavy burdens that disenfranchised women bear.[9]

We join other commentary, approaching the subject from a unique angle and adding our voices to those of other authors in order to emphasize the urgent need and necessity for change.[10] We differ from other commentary, however, in that we believe there is still a necessity for federal oversight, albeit federal oversight with increased flexibility.

Sterilization Background

In the United States, female sterilization, often done postpartum, is a popular choice of contraception due to its efficacy and safety.[11] After prenatal counseling for sterilization, half of the women who report choosing to have a postpartum tubal ligation had the procedure performed at the time of delivery.[12] One investigator reported that almost 47% of women who desired a postpartum tubal ligation, but did not receive one, conceived within one year. This is double the rate of patients who do not request postpartum sterilization.[13]

Unfortunately, for some women, their desire for this procedure is not met due to social, legal and financial barriers. This is particularly true for underserved women, who have low social economic status, receive welfare, and/or have no insurance. The results are often unintended pregnancies.[14]

Such unintended pregnancies in United States are significant consequences for the affected women, their offspring, and society. These unintended pregnancies are associated with worse perinatal outcomes, such as higher rates of maternal morbidity and mortality, low infant birth weight, infant mortality, and developmental delay.[15]

The unintended pregnancies are more likely than planned pregnancies to become a social and economic burden on the population and the health care system with annual public costs of billions of dollars.[16] This may be especially true with increased access to health care services resulting from the Affordable Care Act.[17] One cost analysis estimated the direct annual public cost of not fulfilling women's requests for postpartum sterilization at $215 million.[18]

For many underserved women, their postpartum hospital stay is not only convenient, but more importantly it is the only feasible time to have the sterilization procedure performed. Sterilization during the postpartum period avoids an additional hospital admission that would cause added strain on homeless and disenfranchised women whose days are filled with complicated housing issues, child care issues, and other various socioeconomic issues.

Underserved Women Face Many Barriers in Access to Postpartum Sterilization

(1) **Age of woman:** Although Medicaid funds sterilization for women who are older than 21 years of age, many physicians are hesitant to sterilize women under 30 years of age, because of a concern that younger women are more likely than their older counterparts to regret their sterilization decision.[19]

(2) **Religious affiliation hospital restriction:** Catholic hospitals are the single largest group of nonprofit hospitals in United States and represent 10-11% of all hospitals nationwide.[20] Sterilization for men and women is not permitted in Catholic hospitals and health care institutions.[21]

(3) **Federal funding policy and consent regulation:** Medicaid coverage of sterilization procedures in non-emergency cases requires the sterilization consent to be signed 30 days prior to the date of the procedure. Such consent remains valid for only 6 months. To perform the procedure during an emergency abdominal surgery or premature delivery, the consent must have been signed at least 3 days prior to performing the procedure.[22]

(4) **Consent forms should be present or verified before the procedure:** This requirement relies on meticulously kept medical records, and/or the patient must bring her own copy of the consent to labor and delivery. Understandably, groups such as homeless and/or underserved women may have significant obstacles to storing and bringing their signed consent to labor and delivery, to avoid having the procedure cancelled.[23] Electronic medical records may provide a solution to this barrier for a single health care system. However, since many disenfranchised women often receive fragmented health care and are frequently forced to relocate, even in the current era of transition to electronic medical records, having a copy of the consent may remain a barrier.

(5) **Shortage of operating room accessibility:** Optimally, the postpartum sterilization procedures can be done on the operating table in the labor

and delivery room. Hospital logistics can present barriers to having a tubal ligation during the immediate postpartum period. A busy labor and delivery unit with limited resources or medical staff may result in the procedure being cancelled and rescheduled six or eight weeks after delivery, at a time when the patient may once again be pregnant.[24]

A postpartum sterilization procedure is an "elective, non-urgent" procedure that can be postponed until the labor and delivery ward is stable, when enough medical staff is available and no expected urgent case is pending. We agree with the recommendations outlined in the American College of Obstetricians and Gynecologists Committee Opinion #530, July 2012 (Reaffirmed 2014) that:

(1) Sometimes it is more feasible to schedule and perform the procedure in the main operating room of the hospital rather than in the labor and delivery operating room.[25]

(2) Due to the critical nature of the time to perform the procedure and the consequences of missing that window, the procedure should be considered as an important and crucial procedure that needs to be done urgently rather than just as an elective case that can be postponed.[26]

(3) For the procedure, collaboration between the OB/GYN, anesthesiologist, nurses and various health care and administration staff is necessary. All must work as patient advocates.[27]

Brief History of Medicare Policy Funding Postpartum Sterilization[28]

With expansion of the tubal ligation method of contraception in 1960s and 1970s, federal funding for family planning programs became available. Unfortunately, also during that era, several sterilizations were performed without patients' informed consent. Most victims of these practices were minorities or immigrants living in poverty. The government programs that funded these family planning programs were accused of promoting racial, ethnic, and socioeconomic eugenics.[29]

During mid-seventies, the Department of Health, Education and Welfare created legislation and regulations to protect vulnerable populations from similar acts. In order to receive federal funding for sterilization procedures, the Department of Health, Education and Welfare requires:

(1) No sterilization of people under 21 years of age, institutionalized, or mentally incompetent.

(2) A 3-day waiting period between signing the informed consent and performing the procedure.

(3) In 1978 the federal 3-day waiting period was extended to a 30-day period that matched the sterilization consent procedures adopted in New York City designed to address documented abuses in the Health and Hospital Corporation.

Despite numerous social, economic and logical changes affecting the lives of underserved women, there have been no significant changes since 1978.

The regulations have not been changed significantly since the 1970s. Now, in order to qualify for federal coverage of sterilization:

(1) Women must sign a consent form one month in advance.

(2) The consent is only valid for 6 months (180 days).

(3) A copy of the signed consent form must be present or verified before the procedure is performed.

(4) In case of an emergency or premature delivery, there must be 3 days between when the consent is signed and the procedure is performed.

Ethical Demand and Necessity of Change

Even though the original purpose of the federal family planning legislation and regulations that created the Title XIX consent sterilization form was to protect vulnerable, underserved women, there is now evidence that this process harms the target group rather than protects them.[30] Moreover, this consent procedure violates the basic principles of medical ethics.[31] The legislation does not meet the justice standard, and fails to grant equal opportunity to access the health care system. For example, with the exception of New York City, patients with private insurance do not have to comply with time frame restrictions between their consent and the procedure.[32] Women whom the regulations were designed to protect often present with a valid request for sterilization and for a variety of reasons are not able to have a postpartum tubal ligation. This creates a multiclass reproductive health care delivery system, differentiating between women with public insurance and women with private insurance.[33]

Recent literature confirms that the regulations violate and breach basic ethical values and rights of these women by restricting and limiting their access to the health system, and the regulations have not been revised significantly since their inception.[34][8, 20-23] The federal regulations limit contraception options (a violation of autonomy), increase women's risk of unintended pregnancy and poor perinatal outcomes (a violation of nonmaleficence), and when compared to health care for their wealthy counterparts, such legislation fails to provide what is necessary and good for poor women (a violation of both beneficence and justice).[35]

Conclusion

We agree with others calling for a modification of the Title XIX consent for sterilization. To address the problem of missed postpartum tubal ligations, we suggest:

- Women have the right to be fully informed about the procedure and freely chose to have the appropriate method of sterilization during the immediate postpartum period.
- A safe, reliable, rapid method must be developed to store and retrieve the sterilization consent form.
- Improvement of accessibility for underserved women to postpartum sterilization and evaluate the feasibility of modifying or eliminating limitations and barriers to facilitate their request.
- Modify by expanding the 30-day waiting rule.
- Modify by expanding the 180-day expiration rule.
- Create better methods to ensure the postpartum sterilization procedure can be performed in a timely manner. For example, consider scheduling the procedure in the main operating room or make it a hospital priority so the procedure can be done prior to discharge.

Endnotes

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2. Herbert B. Peterson et al., *The impact of laparoscopy on tubal sterilization in United States Hospitals, 1970 and 1975 to 1978*, 140(7) Am. J. Obstet. Gynecol. 811 (1981).
3. *Relf v. Weinberger*, 372 F. Supp. 1196 (D.D.C. 1974).
4. *See* Sonya Borrero et al., *Medicaid Policy on Sterilization—Anachronistic or Still Relevant?*, 370(2) N. Engl. J. Med. 102 (2014); *see also* Committee on Health Care for Underserved Women, *Committee opinion no. 530: access to postpartum sterilization*, 120(1) Obstet. Gynecol. 212 (2012); *see also* Nikki Zite and Sonya Borrero, *Female sterilisation in the United States*, 16(5) Eur. J. Contracept. Reprod. Health Care 336 (2011); *see also* American College of Obstetrics and Gynecology, *Practice Bulletin no. 133: Benefits and Risks of Sterilization*, 121(2) Obstet. Gynecol. 392 (2013).
5. *See* Borrero, *supra* note 4; *see also* BP Brown and Julie Chor, *Adding Injury to Injury: Ethical Implications of the Medicaid Sterilization Consent Regulations*, 123(6) Obstet. Gynecol. 1348 (2014); *see* Nikki Zite et al., *Barriers to obtaining a desired postpartum tubal sterilization,* 73(4) Contraception 404, 2006; *see also* Sonya Borrero et al., *Federally funded sterilization: time to rethink policy?* 102(10) Am. J. Public Health 1822 (2012).
6. *See* Borrero, *supra* note 4; *see also Committee opinion no. 530*, *supra* note 4; *see also* Brown and Chor, *supra* note 5; *see also* Zite et al., *supra* note 4; *see also* Borrero et al., *supra* note 4; *see generally* Thomas Beauchamp and James Childress, Principles of Biomedical Ethics (New York: Oxford University Press, 6th ed. 2009); *see* Jessica Gipson et al., *The effects of unintended pregnancy on infant, child, and parental health: a review of the literature.* 391(1) Stud. Fam. Plann. 18 (2008); *see* Sonya Borrero, Cara Nikolajski, et al., *"Everything I Know I Learned from My Mother...or Not": Perspectives of African-American and White Women on Decisions About Tubal Sterilization,* 24(3) J. Gen. Intern. Med. 312 (2009).
7. *See* Borrero, *supra* note 4; *see also Committee opinion no. 530*, *supra* note 4; *see also* Brown and Chor, *supra* note 5.
8. *See* Borrero, *supra* note 4; *see also Committee opinion no. 530*, *supra* note 4; *see also* Brown and Chor, *supra* note 5.
9. *See* Christine Dehlendorf et al., *Disparities in Family Planning*, 202(3) Am. J. Obstet. Gynecol. 214 (2010); *see also Committee opinion no. 530*, *supra* note 4; *see also* Borrero et al., *supra* note 4.
10. *See* Borrero, *supra* note 4; *see also Committee opinion no. 530*, *supra* note 4; Brown and Chor, *supra* note 5; *see also* Zite et al., *supra* note 4; *see also* Borrero et al., *supra* note 4.
11. *See* note 3 *supra*.
12. *See* Nikki Zite et al., *Failure to obtain desired postpartum sterilization: risk and predictors,* 105(4) Obstet. Gynecol. 794 (2005).
13. Sonya Borrero et al., *Unintended pregnancy influences racial disparity in tubal sterilization rates*, 25(2) J. Gen. Intern. Med. 122 (2010); AR Thurman and T Janecek, *One-year follow-up of women with unfulfilled postpartum sterilization requests.* 116(5) Obstet. Gynecol. 1071 (2010); *see also* Borrero, *supra* note 4; *see also* Brown and Chor, *supra* note 5.
14. Borrero, S., et al., *Unintended pregnancy influences racial disparity in tubal sterilization rates,* 25(2) J. Gen. Intern. Med. 122 (2010); Borrero, *supra* note 4; *see also Committee opinion no. 530*, *supra* note 4; Brown and Chor, *supra* note 5; *see also* Zite et al., *supra* note 4; *see also* Borrero et al., *supra* note 4; Borrerro, Nikolajski, et al., *supra* note 6; Zite et al., *supra* note 5.
15. Borrero, *supra* note 4; *see also Committee opinion no. 530*, *supra* note 4; Gipson et al., *supra* note 5; Thurman and Janecek, *supra* note 13.
16. James Trussell, *The cost of unintended pregnancy in the United States.* 75(3) Contraception 168 (2007).
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22. 42 C.F.R. § 441.257 (1976); 42 C.F.R. § 441.253 (1976); 42 C.F.R. 441.253 (1978); Brown and Chor, *supra* note 5; Borrero et al., *supra* note 4; Zite et al., *supra* note 4.
23. Borrero, *supra* note 4.
24. *Committee opinion no. 530*, *supra* note 4; *Practice Bulletin no. 133: Benefits and Risks of Sterilization*, *supra* note 4.
25. *Committee opinion no. 530*, *supra* note 4.
26. *Id.*
27. *Id.*
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supra note 4; Brown and Chor, *supra* note 5; Borrero et al., *supra* note 4; Zite et al., *supra* note 5.

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33. Lawrence, *supra* note 31; Borrero, *supra* note 4; Brown and Chor, *supra* note 5; Borrero, *supra* note 5; Beauchamp and Childress, *supra* note 6.

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Everyone Deserves a Proper Burial: Cultural, Ethical, and Religious Issues Associated with Current Autopsy Procedures

By Matthew W. Cramer

Introduction

Imagine a scenario in which an individual unexpectedly and tragically dies and the cause of death is unknown. Assume the coroner obtains consent from the family to conduct an autopsy, but the cause of death cannot be determined. The decedent's family and next of kin ask for the body to bury their loved one. The coroner agrees to deliver the body to the family but decides to retain the individual's heart and brain for further examination. The family is not informed of his actions. Within a few days, the family schedules a funeral and buries the body. In the meantime, the coroner continues to examine the individual's heart and brain for several weeks to determine the cause of death. Weeks after the funeral, the coroner delivers the autopsy report to the family outlining the procedures performed and his findings. Naturally, the family is troubled by the fact that the cause of death is still unknown, but as they continue reading the report, they are even more upset to discover that they buried their loved one without his or her heart and brain!

Actually, this scenario is not imaginary at all, but has happened often as a result of current autopsy procedures.[1] Part I of this article will discuss what an autopsy entails and how autopsies are currently conducted. Part II will discuss why autopsies have religious, social, and cultural importance. Part III will discuss how courts and legislatures have dealt with autopsies and post-mortem organ retention. Part IV will discuss the protections that are in place that allow families to bury loved ones. Part V will discuss the religious protections that are in place with respect to burial. Part VI will discuss a potential solution to the issues that arise during an autopsy, relating to organ retention.

I. What Is an Autopsy?

An autopsy, also referred to as a post-mortem examination or necropsy, involves examining the body of a dead person to determine the cause of death, diagnose diseases, or analyze whether a particular treatment was successful.[2] Autopsy means "the external and internal examination of the body of a deceased person, including, but not limited to, gross visual inspection and dissection of the body and its internal organs…and the retention for diagnostic and documentary purposes of tissues, organs, blood, other bodily fluids, gases, or any other specimens as the examining individual considers necessary to establish and defend against challenges to the cause and manner of death."[3]

An autopsy consists of an entire examination of the body, both internal and external.[4] The external examination consists of a careful inspection of the body.[5] The examiners "weigh and measure the body, noting the subject's clothing, valuables, and characteristics such as eye color, hair color and length, ethnicity, sex, and age."[6] Once the decedent's clothes are removed, the examiners look for scars, tattoos, or injuries on the body.[7]

The internal examination of the body involves making a Y-shaped incision in the trunk of the body extending from each shoulder to the bottom of the breastbone.[8] First, the body is placed on a slanted table designed with several nozzles and raised edges for running water to wash away and drain all the blood that is lost during the procedure.[9] Once "the body is positioned, the [examiner] places a 'body block' under the patient's back" to gain better access to the trunk for the incisions.[10] The examiner takes a large scalpel and makes a very deep incision into the trunk of the body.[11] Once the incision is made, the examiner peels back the skin, muscle, and tissue of the body and pulls it over the patient's face so that the rib cage and inner muscles are exposed.[12] According to Ed Uthman, a diplomate of the American Board of Pathology, human muscles smell like raw lamb meat.[13] Next, an electric saw is used to cut through the rib cage to reach the heart and the lungs, the organs of the chest.[14] The examiner cuts open the outer layer that covers the heart and sticks his finger into the hole in the artery to feel around for any blood clots that may have lodged there and caused death.[15]

Now that the body is open and accessible, the next step is to remove the organs from the body. This step is similar to field dressing a deer.[16] The procedure begins at the top and progresses downward so that all the organs are removed from the body in one piece.[17] The examiner takes the chunk of organs to another table for individual dissection of the organs.[18] The next step is to remove the brain. The process of removing the brain is similar to removing bodily organs.[19] A "body block" is placed under the patient's head and a scalpel is used to cut from behind one ear to behind the other ear.[20] The front portion of the scalp is pulled over the patient's face, while the back portion is pulled over the patient's neck.[21] Uthman describes the sound of removing part of the skull as a "combination of a sucking sound and the sound of rubbing two halves of a coconut together."[22] Once the brain is exposed, it is relatively easy to remove it from the skull, but because the brain is mushy and re-shapeable, it is not inspected

during the autopsy.[23] Instead, it is placed in a preserving solution for a few weeks to harden the brain, making it easier to handle.[24]

Over at the other dissection table, the examiner pulls apart and separates the individual organs.[25] Each organ is removed, weighed, sliced, and examined.[26] Organs such as the intestines and the stomach need to be cleaned out before being examined.[27] "The intestines are [ ] opened over a sink under running water, so that all the feces and undigested food flow out."[28] "The resultant material in the sink smells like a pleasant combination of feces and vomitus."[29] Similarly, if the patient has eaten solid food, the contents may appear in the stomach and the stomach must also be washed out.[30] The majority of the organs are sampled and cut into pieces the size of postage stamps and placed in plastic bags.[31] Even the major organs are sliced and kept in jars with preservation solution.[32] All the "leftover" pieces of the body are incinerated.[33]

At this point, the autopsy room is a complete mess. The table where the body is laying is usually covered and dripping with blood.[34] The hanging scales used to weigh each of the organs are usually dripping with blood.[35] Even the examiner's utensils are sometimes smeared with blood.[36]

"The body is now an empty shell, with no larynx, chest organs, abdominal organs, pelvic organs, or brain."[37] To get the body ready for a funeral, the skull of the brain is replaced, but not the brain itself, and the scalp is sewn back together.[38] At this stage, Uthman describes the body as "the hull of a ship under construction, the prominent ribs resembling the corresponding structural members of the ship."[39] In some cases, but not all, the chopped up organs are placed in bags to prevent leakage and thrown back into the body, while other times the organs are incinerated.[40] If the organs were not replaced in the body, the examiner places "filler" in the body, such as cotton or wool,[41] so that the trunk keeps its shape and does not appear disfigured.[42] "[W]hat is buried/cremated is either 1) the body without a brain and without any chest, abdominal, or pelvic organs, or 2) the body without a brain but with a hodgepodge of other organ parts in the body cavity."[43] Finally, "[t]he [examiner] rinses the body off with a hose and sponge, covers it with a sheet, and calls the funeral home for pick-up."[44]

Days, sometimes weeks, later, the pieces of retained organs and the brain that were left in a jar of preservation solution are examined.[45] After being in the preservation solution, Uthman describes the consistency of the brain as a "ripe avocado."[46] Before being "fixated" by the solution, the consistency of the brain resembles "three-day-old refrigerated, uncovered Jello."[47] The brain is then sliced up and put on a tray for examination.[48] Some pieces are sliced for microscopic examination and others are put back in preservation jars.[49] The leftover slices of the brain are incinerated without ever being returned to the family.[50]

II. Social, Religious, and Cultural Importance of Autopsies

i. Social Importance

Autopsies are authorized as an exercise of the State's police powers.[51] The State's police powers consist of promoting the health, safety, and general welfare of the public.[52] With respect to public health, autopsies play a critical role in the identification of contagious diseases and in preventing their spread.[53] Organs such as the brain and heart are particularly valuable in finding the diseases that can cause a person's death.[54] Autopsies are also an important part of many criminal investigations.[55] Many times, the evidence collected from an autopsy leads to efficient arrests and convictions.[56]

ii. Religious Importance

Just as the practice of religion has been around for millions of years, "respectful funeral rites are as old as humanity itself."[57] Most religions and cultures throughout the world stress the importance of a proper burial and believe in some kind of afterlife, whether it is reincarnation, spiritual existence, purgatory, or heaven.[58] Even though "the corpse has [] universal importance as a symbol, its precise significance for the individual or society will differ according to the particular [religion] adopted."[59] Some religions and cultures embrace the importance of burying a loved one fully intact.[60] "[Other] religious and cultural groups ascribe different [ ] values to [different] body parts and [ ] these [values] change over time."[61] The following descriptions of three religions and their beliefs regarding the burial of the dead will illustrate the importance of treating bodies and body parts with respect.

a. The Hmong Culture

The Hmong culture first began to appear in the United States in the 1970s, when many Hmong decided to relocate to other countries to escape oppression and harsh living conditions.[62] As of 2010, "260,073 persons of Hmong origin were counted in the 50 U.S. states,… [which] represents a forty percent increase from…2000."[63] "For those who immigrated to the United States…many families experienced extreme culture shock: transitioning from cooking in mud stoves to switching on a button for cooking; from burning wood to turning on a button for heat."[64] Despite all the technological, educational, and cultural advances that many Hmong experienced when they reached the United States, one aspect of Hmong culture that remained largely unaltered was the Hmong funeral rituals.[65] These rituals and the roles and duties of each member of the family in performing them have been passed down from generation to generation.[66]

The Hmongs believe that "a proper burial [] will ensure 'health, safety, and prosperity for the deceased[.]'"[67]

The Hmong people believe in multiple life cycles; death is the end of one cycle, while reincarnation is the beginning of another.[68] It is believed that without a proper burial, any Hmong who dies will not be able to connect with his or her ancestors in the afterlife.[69] The majority of Hmong practice Animism, "a belief that every living thing has a spirit or soul."[70] For generations, the Hmong have worshipped and respected the spirits and souls of their ancestors.[71] In the course of a Hmong New Year celebration, families invite the spirits of their ancestors to join in the festivities.[72] This invitation helps ensure protection, and good health, and "brings fortune to families."[73]

Death is a sensitive subject to discuss in the Hmong culture. Despite their significant burial rituals, the open discussion of death or "preplan[ing] funeral[s]" is frowned upon because it is thought to "bring bad luck or disharmony among household spirits and upset household guardians."[74]

Traditional funeral rituals generally last three to seven days, depending on the age of the deceased.[75] "The Hmong set [] burial [dates] based on the lunar calendar."[76] The burial date helps determine the deceased's next life and whether he or she will "'bring wealth, prosperity, stability, and nobility' for his/her descendants."[77] A timely burial date and an appealing burial site help determine the deceased's success in the afterlife.[78]

Most Hmong believe that "[i]f the body is cut or disfigured, or if it loses any of its parts, it will remain in a condition of perpetual imbalance, and the damaged person not only will become frequently ill but may be physically incomplete during the next incarnation[.]"[79] "If people lose their vital organs after death, their souls cannot be reborn into new bodies and may take revenge on living relatives; so autopsies and embalming are [] taboo."[80]

b. Judaism

2.2 percent of the American population is Jewish.[81] It is estimated that there are 5.3 million Jewish adults and 1.3 Jewish children in America.[82] Jews believe that the decedent's body belongs to God and should not be disrespected because the body holds the soul.[83] The body is thus a holy vessel and must be treated with dignity.[84] "[O]rthodox Jews resist autops[ies] because for them it is important to keep the body whole."[85] "The ancient Hebrews, in practices that continue in Orthodox Judaism, insisted upon the immediate burial of their dead and a ritualized period of mourning for the family and community. The continuing concerns about the 'uncleanliness' of the corpse and desecration of the body by cutting into it—'mutilation'—have shaped a long tradition of resistance to autopsies and the dissection of Jews for teaching purposes."[86]

Jewish burials must take place as soon as possible after death in order to honor the dead.[87] Burial should only be delayed for one day when there is not enough time to bury the body before Shabbat or a holiday.[88] "Anything less is considered a 'humiliation of the dead[.]'"[89] The Jewish tradition requires someone to accompany the body of the deceased at all times from the time of death until the body is buried.[90] Traditional Jewish rituals require "immediate relatives of the deceased [to]…tear their garments to symbolize their loss."[91] Reformed Jews perform this step a little differently by allowing the rabbi to tear black ribbons for the family to pin on their clothes to symbolize the loss.[92] When a Jew dies, the body is arranged for burial through a process called the Tahara, which is conducted by other Jews, usually family or friends.[93] During this process, the decedent's body is physically washed with water, dressed in burial garments, and placed in the casket.[94] Under Jewish law, a simple pine box must be used to bury the body and cremation and embalming is forbidden.[95] Generally, "[m]en prepare men and women prepare women."[96] The decedent is placed in white burial clothing to "avoid distinguishing between rich or poor."[97] At the cemetery, it is a common tradition for the coffin to stop seven times on its way to the gravesite.[98] Once the coffin is placed in the grave, family and friends throw handfuls of dirt over the coffin.[99] After the burial, the family of the deceased usually sits Shiva for three to seven days.[100]

A major part of the Jewish tradition is to refrain from preserving or mutilating the body of the deceased.[101] If an autopsy is required, it is expected that the body will be sewn back together tightly.[102] Only the necessary body parts should be removed from the body and all the fluids, blood, and organs should be put back into the body cavity.[103] It is believed that "…the blood of a person is considered as holy as his life and deserves proper burial[.]"[104]

c. Islam

A common belief among many Muslims is that the good deeds performed throughout one's life will provide access into paradise when the world is destroyed.[105] Until the Last Day (Day of Judgment), "the dead remain in their tombs, and those heading for Paradise will experience peace while those heading for Hell will experience suffering."[106] According to Islamic law, the body of the deceased must be buried as soon as possible.[107] Generally, autopsies are considered unacceptable in Islam because it is seen as desecration of the body and, in many cases, family members of the deceased refuse to allow an autopsy to be performed.[108] "Embalming and cosmetology are not allowed unless required by state or federal law."[109] Many Muslims believe the body must be buried fully intact because a person's soul is found in the heart and consists of both good and evil.[110]

Due to the need to bury the body of the deceased as soon as possible, there is no viewing of the body at or before the funeral.[111] In preparation for burial, the body of the deceased "must be washed and shrouded."[112]

"The body should be washed three times"[113] or an odd number of times until it is entirely clean and "should be washed in the following order: upper right side, upper left side, lower right side, lower left side."[114] When the cleaning of the body is finished, the body is covered in a white sheet.[115] To shroud the body, the body is placed on top of three large white sheets, which are then wrapped around the body and secured with ropes.[116] At the cemetery, "[o]nce the body is in the grave, a layer of wood or stones should be placed on top of the body to prevent direct contact between the body and the soil that will fill the grave."[117]

The idea of placing such importance on the heart is not novel; it has persisted throughout the centuries. In Ancient Egypt, "[a]n important part of the Egyptian soul was thought to be the the *lb*, or heart."[118] "In Egyptian religion, the heart was [also] the key to the afterlife."[119] "[I]t was the heart and not the brain that was the seat of emotion, thought, will, and intention."[120]

iii. Cultural and Symbolic Significance

Many Western cultures associate the soul with the mind/brain. For example, during the Terri Schiavo case—which involved deciding whether to continue life support for an individual in a permanent vegetative state—people suggested that it was morally acceptable to let her die because she had irreversible brain damage.[121] This argument "equate[d] the human brain with the human 'mind' and that when the brain is 'irreversibly' damaged, the 'person' no longer exists since the 'mind' no longer functions."[122]

"Hearts, blood, [and] brains [ ] have long seemed more powerful, more central to personhood, or more attuned to spiritual connections than hair, saliva, leg muscles, or kidneys."[123] Since the heart and brain shape the meaning and value of the body to many people, medical examiners need to be aware of these beliefs when performing autopsies. In most cultures, the brain and/or the heart are considered the major organs of the body.[124]

Penalties for grave robbing and corpse abuse were created to protect the integrity and dignity of the deceased.[125] Eulogies and ceremonial awards are sometimes presented to the deceased and his or her family.[126] Culturally, people find comfort in knowing their loved ones are buried with their name, reputation, and image untarnished.[127] "The image of the decedent in the minds of others should not be undervalued."[128] All the pain and suffering felt by the decedent's family and friends partially subsides when they know they have done all they can to assure their loved one is buried respectfully.[129]

The performance of autopsies is a vital aspect of public health and welfare.[130] In order to conduct autopsies responsibly and intelligently, medical examiners must remember they have a professional and ethical responsibility to the families of the deceased. Failing to meet this responsibility may have adverse effects on members of society.

III. How the Courts and Legislature Have Dealt with Autopsies and Organ Retention

The current policies for conducting autopsies have created significant obstacles to those with religious or cultural concerns who wish to give their loved ones what they deem a proper burial. Courts and legislatures have handled these concerns by framing and interpreting the law inconsistently. Organ retention is regulated in the United States under state law.[131] But the state legislatures and courts disagree on whether standards for post-mortem organ retention are really needed, and even when they determine standards are necessary, the legal framework to be used in restricting/regulating these standards is uncertain.[132]

A story written in a letter from a medical student to his family in the nineteenth century indicates that physicians performed autopsies in the 1800s regardless of whether they obtained permission to do so.[133] The student argued that "such practices added excitement to medical life, presumably removing a part, such as the heart or stomach, could be easily justified and then disguised by adding stuffing, closing the incision, and placing the corpse in a shroud."[134]

More recently, in 1974, after a twenty-eight-year-old died in a car crash, medical examiners obtained consent to perform an autopsy but failed to mention that they were going to retain and preserve some of her organs.[135] Twenty years later, her parents found out that scientists retained and stored tissue samples.[136] The decedent's father argues he had never consented to the retention of his daughter's organs and stated "[t]hey had no business taking her body in the first place."[137] He also stated that "'[w]e only gave them permission to do an autopsy. That had nothing to do with stripping her body organs out' and taking them[.]"[138]

Most recently, in 2011, the U.S. Office of Special Counsel found that there was "gross mismanagement" of the Air Force base mortuary.[139] There were "missing body parts, fetal remains stored in cardboard boxes, and a dead Marine's arm sawed off, without family consent, to fit his body into his uniform."[140] An investigation revealed that on two separate occasions body parts of service members were lost by the mortuary and not reported to families.[141] The Air Force argued that since there is no specific law that requires officials to notify family members about the misplacement of body parts, their actions were not illegal.[142] Furthermore, the Air Force argued that families give the military "implied consent" to arrange bodies for funerals and viewings.[143]

In a letter written to President Obama, U.S. Special Counsel Carolyn Lerner stated, "The fact that there is no specific provision for a scenario [like this]…does not

remove the question of whether a duty was owed to inform the families[.]"[144] One funeral director who has been employed for forty years stated, "It would never [have] been permissible to significantly alter a corpse without the family's consent."[145] In response to the Air Force's argument that its actions were not illegal, one of the whistleblowers who revealed the scandal stated, "We ask for permission to remove a beard or mustache; why would we not request permission to remove a major bone?"[146] After the scandal was publicized, the Air Force decided to inform the families of the incidents that occurred regarding their loved one's remains and decided to reprimand three officials by demoting them.[147]

In general, the dissection of the body of a human being is illegal if not authorized by law or agreed to by the deceased or the deceased's family.[148] In New York, the Public Health Law allows dissection of dead bodies only where it is (1) prescribed by statute, (2) authorized by the surviving spouse or next of kin, (3) ordered by the court to ascertain the cause of death, or (4) performed in the course of an investigation involving the possibility of criminal activity.[149] The policy behind this rule is to allow the relatives to have possession and control of the remains of a decedent unless there are strong countervailing considerations.[150] Interestingly, the Public Health Law requires hospitals to obtain consent before performing an autopsy, but does not require medical examiners to obtain consent.[151] Medical examiners have the ability to obtain and retain a decedent's organs for further study without consent and cannot be held liable.[152]

Although medical examiners are not required by law to obtain consent from family members, families are routinely given standard autopsy consent forms to sign.[153] The forms state "I/we authorize the removal and retention or use for diagnostic, scientific, or therapeutic purposes [of] such organs, tissues, and parts as such physicians and surgeons deem proper."[154] Family members do not even have to see the form to give consent; their consent may be taken over the telephone.[155] Since consent is not required by law and families may not have the form in front of them, they may consent without hearing or understanding all the terms.[156] More specifically, family members may not understand that a decedent's brain, heart, or other vital organs may be retained even after burial of the decedent.[157] Even if families do notice the retention clause, they are likely to think that it refers to small tissue samples and not whole organs or that the organs will be returned prior to burial.[158]

Another major problem that arises when dealing with autopsies and organ retention is that courts and statutes have framed and interpreted the issue using the term "the body" when instructing physicians on what to do with the decedent's body.[159]

For example, one Michigan statute "authorizes Medical Examiners to retain, 'as long as may be necessary, any portion of the body believed by the medical examiner to be necessary for the detection of any crime.'"[160] However, that same statute also states that medical examiners should "promptly deliver or return *the body* to relatives or representatives of the deceased."[161] "The statutory language does not specify whether each and every body part or specimen collected during the course of an autopsy must be returned to the next of kin when it is no longer needed, perhaps on a piecemeal basis."[162]

Many state statutes protect against autopsies if they violate the family's religious or cultural beliefs; however, the powers given to medical examiners make it easy to undermine these protections. For example, a New York statute states that "in the absence of a compelling public necessity, no dissection or autopsy shall be performed over the objection of a surviving relative or friend of the deceased that such a procedure is contrary to the religious belief of the decedent[.]"[163] This statute puts the burden of objection on the family member instead of putting the burden on the coroner to ask whether an autopsy would offend the family's religious beliefs. Since the law does not require consent, a coroner need not make an effort to obtain consent and can just assume that an autopsy would not be offensive.[164]

Other jurisdictions have decided the families' rights to organ retention from autopsies by choosing whether to recognize a property right in a dead body. For example, in Arkansas, courts recognize that "the next of kin does have a quasi-property right in the dead body."[165] A quasi-property right refers to the limited right of the next of kin "to gain custody and possession of a body for as long as necessary until proper disposition."[166] Despite recognition of a quasi-property right to a dead body, courts in Arkansas have not decided whether this right extends to all of the body's organs.[167] On the other hand, Colorado and Mississippi do not recognize any property right in a dead body.[168] Under Mississippi law, courts have stated that the family has a right to possess the "body" for burial purposes but that right does not create a property right in the organs removed for examination.[169]

Similarly, in Ohio, "[t]he next of kin, other relatives, or friends of the deceased person, in the order named, shall have prior right as to disposition of the body of such deceased person."[170] Ohio courts have interpreted this statute to mean that a dead body is not property and "have rejected the theory that a surviving custodian has a quasi-property right in the body of the deceased."[171] In 2006, the Ohio General Assembly enacted legislation in an attempt to give guidance to courts when dealing with cases involving body parts retained from an autopsy.[172] The legislation states that "retained tissues, organs, blood, other bodily fluids, gases, or any other specimens from an autopsy *are medical waste* and shall be disposed of in accordance with federal and state laws[.]"[173]

Furthermore, according to Ohio law, "if an autopsy is performed on a deceased person and the coroner has reason to believe that the autopsy is contrary to the de-

ceased's religious beliefs, the coroner shall not remove any specimens, including, but not limited to, tissues, organs, blood, or other bodily fluids, from the body of the deceased person unless it is a compelling public necessity."[174] If the specimens are removed, "the coroner shall return the specimens, as soon as is practicable, to the person who has the right to the disposition of the body."[175] Once the coroner knows that an autopsy is against the decedent's religious beliefs, the coroner must delay the autopsy and "give the objecting person time to file suit to enjoin the autopsy."[176] The coroner does not have to obtain consent from the next of kin of a decedent in order to perform an autopsy and the coroner's duty to perform an autopsy outweighs the decedent's or next of kin's wishes to donate a body part.[177] Essentially, the next of kin have a right to disposition of the body, but only after the coroner has performed his duties.

In specific circumstances, such as violent or unusual causes of death, many states authorize a coroner to perform an autopsy without obtaining consent.[178] The majority of states are silent on the issue of organ retention; only one state, Mississippi, has established a limit on the authority of physicians to retain body parts.[179] The statute does not require coroners to obtain consent to an autopsy or give family members notice prior to disposal, but it allows the next of kin to apply in advance and in writing to prevent retention and destruction of organs.[180] It states that a physician is authorized to dispose of the retained body parts through incineration, cremation, or burial "unless he shall have been furnished prior to removal or acquisition of the tissue, or at any time prior to its disposal, a written request that the same be delivered to the patient or someone in his behalf or, if death has occurred, to the person claiming the dead body for burial or cremation."[181]

There have been at least two federal cases where courts have extended the rights of family members.[182] In one case, the United States Court of Claims allowed a cause of action for "wrongful retention of remains" and "tortious interference with [Plaintiffs'] right to bury their son."[183] The plaintiffs' child had died accidentally in military housing overseas and was autopsied in a United States military hospital.[184] His internal organs were never found and were presumed incinerated.[185] Due to the absence of an applicable statute, the court allowed the family to bring a claim for wrongful retention of remains.[186] In another precedent-setting case, "the court rejected the defendant's motion to dismiss a claim of un-consensual post-mortem organ retention. There, after general consent for an autopsy had been obtained, a decedent's remains were returned to his sister with all the internal organs missing. Based on its interpretation of New York State law, the district court refused to dismiss a claim relating to 'unlawful retention of internal organs and viscera of the deceased,' citing an absence of express authority in New York statutes for hospitals to retain organs or tissues during autopsy procedures."[187] The court held that despite obtaining valid consent from the plaintiff to conduct the autopsy, there was no authorization to retain any organs.[188]

It is unacceptable to return only the "shell" of a body to the decedent's family, but it would be too time consuming and nearly impossible to ask medical examiners to return all body parts and fluids. However, the major organs such as the brain and heart should always be returned to the family of the deceased if they want them because of their religious and cultural meaning. "[E]ntire corpses [and] significant organs that obviously embody a sense of human identity and personhood, [are] parts that individuals should be able to have disposed of in ways that are meaningful to them."[189]

It is common practice during autopsies for coroners to remove certain organs or body parts and never put them back.[190] When no longer needed, organs such as the brain and heart are usually incinerated because they are seen as medical waste.[191] "Brains are particularly difficult to reunite with a body in time for burial, because it takes three to fourteen days to prepare them for examination."[192] Usually, by the time the coroners are finished with their autopsies, the family members have already claimed the remains from the hospital and buried the body.[193] They are generally unaware that any meaningful body part has been withheld because they are not notified if an organ is retained.[194] "Sometimes brains or other organs are deposited indefinitely in medical center collections without notice to, or consent by, survivors."[195]

One commentator stated: "Imagine that after a post-mortem examination, wedding rings were routinely taken from the deceased's fingers and sold. Or some environmentally minded mortician chose to strip the clothes from the corpse for recycling without any reference to the family. Prosecutions for theft, claims for conversion would follow. If my brain rather than my wedding ring is removed, the law is a mess."[196] Since states know that post-mortem organ retention has become a problem area of the law, why have they not taken action and established a protocol or enacted legislation to deal with post-mortem organ retention?

IV. Protections in Place for Families to Bury Loved Ones

The current policies for conducting autopsies and retaining organs have caused significant problems for the families and friends of decedents who wish to give their loved ones a proper burial.

Each and every state in the United States decided to recognize a property interest in the body when they adopted the Uniform Anatomical Gift Act (UAGA).[197] The UAGA reverses the idea that a person does not have a property interest in the body by allowing for consensual organ donation.[198] While the UAGA creates a property right that allows a decedent's family to object to remov-

ing organs for transplant procedures, many states have refused to recognize this same right in the context of removing organs for autopsy purposes.[199]

Today, there continues to be a grey area "where medical practitioners and scientists take, keep, and use 'worthless' bits of human bodies without questions of law, 'respect,' or responsibility crossing their minds."[200] Despite the Anatomical Gift Act, it appears that as long as the decedent's remains are used for medical or scientific research, there is no violation if major organs are not returned to the family.[201]

The fact that families have no recourse if major organs are not returned for burial is especially surprising given there are laws that prohibit mutilation of the body and defamation of a dead body. For example,"[t]he unlawful and intentional mutilation of a dead body gives rise to a cause of action on behalf of the person [ ] entitled to the possession, control, and burial of such body."[202] Some statutes provide for "criminal liability for unauthorized mutilation or dissection of a dead body[, while others] prohibit the removal, concealment, failure to report the finding of, or the destruction of a dead body or any part of it."[203]

Laws against defaming the dead also protect the family's interests. Although in the United States, defamation is usually limited to the living, there are at least five states that have passed legislation that makes defamation of the dead a criminal offense.[204] An Idaho statute reads, "A libel is a malicious defamation, expressed either by writing, printing, or by signs or pictures, or the like, tending to blacken the memory of one who is dead…[.]"[205] In Georgia, the defamation statute explicitly states "living or dead" when referring to whether a person has committed criminal defamation.[206]

Moreover, there are laws that provide families with a cause of action against someone who has caused them suffering. Claims for intentional infliction of emotional distress have been allowed, for example, when the body of a decedent is dropped in front of the family.[207] In 2012, a woman was forced to bury her mother twice when the cemetery allegedly dropped the casket into the grave.[208] The mother's body was allegedly thrown from the casket and ended up on the bottom of the grave.[209] When the family came to inspect the damage to the casket, the mother's personal items were found underneath the casket.[210] The family also "found mud, leaves and debris on the inside of the casket staining the white interior while mud and abrasions were on the body[.]"[211] No court dates have been set, but the family has made seven complaints, one of which is intentional infliction of emotional distress.[212]

These types of laws recognize the importance of a family member's dead body to individuals who cared for him or her and to society as a whole. A spokesman for the National Military Families Association, speaking about the recent U.S. Air Force scandal, stated "[f]or families to hear this type of news [desecration or mutilation of a loved one's body] is stressful because its already worrisome to send your loved one away,…[and] [t]o think that any disrespect would come to them either intentionally or unintentionally, that's not the type of worry that needs to be on their minds."[213]

V. Religious Protections in Place

The current autopsy procedures "have started to transform practices previously imbued with religious beliefs about life after death and/or specific social rituals that demonstrated 'respect' for dead bodies and their parts."[214] Some religious groups believe that "correct burial, entombment, or cremation of the dead body is necessary for the existence and happiness of the person in the next life, either right after death or at some point in the future."[215]

The United States and all fifty states have enacted at least one statute that is designed to protect individual's religious rights.[216] For instance, the Religious Freedom Restoration Act (RFRA) was enacted in 1993 and is a federal law focused on preventing laws from being created that substantially interfere with a person's right to free exercise of religion.[217] In *City of Boerne v. Flores*, it was determined that RFRA could not be applied to the states and localities because it violated section five of the fourteenth amendment.[218] In response, some states passed their own versions of RFRA that apply to state and local governments.[219] Florida, Texas, Connecticut, and Pennsylvania are only a few states among the eighteen that have chosen to adopt their own version of RFRA.[220]

In addition, many state statutes protect an individual's religious rights with respect to burial. In Illinois, any contract between a cemetery and a cemetery's worker's association that prohibits the burial of remains on Sundays or holidays is considered void.[221] Also, it is unlawful to interfere with the burial of a decedent whose religious beliefs require burial on a Sunday or holiday.[222] Tennessee enacted the abuse of a corpse statute, which "applies to physical abuse of human remains, either before or after they have been buried, digging up human remains that have been buried, or to disposing of human remains without a proper burial or cremation."[223] Despite each state's attempt to sufficiently protect an individual's religious rights with respect to burial, state statutes and legislation have failed to provide sufficient protections relating to major bodily organs.

VI. A Possible Solution

The United States is a melting pot consisting of multicultural and multi-religious groups. Despite all the federal, state, and local laws addressing autopsy procedures and the retention of organs, many cultural and religious groups are being denied the chance to bury their loved ones in accordance with their cultural/religious beliefs.

To protect the rights of these individuals, each state should require that families be given notice when the heart or brains are going to be retained, and an opportunity to re-acquire the retained organs for burial.

First, even the possibility that decedent's organs will be retained should be divulged to the family. Preferably, if the family is interested, a medical examiner should take the time to discuss the situation with the families and provide them with the necessary information regarding the condition of the decedent's body. Medical examiners should discuss the organ retention process with the families so that there is no expectation of getting the body returned in the same or a similar condition as before the autopsy. On the other hand, due to the grisly nature of the organ retention process, it is understandable if some families would prefer to not hear about the process at all. The more informed the families are, the more likely they will be willing to accept autopsy procedures without objection.

Second, families and next of kin should be given notice when the heart and/or brain have been retained. Realistically, it would be absurd to ask medical examiners to collect and return every single part of the body. The loss of water, blood, and small pieces of tissue is unavoidable. However, due to the heavy religious and symbolic meaning many religions and cultures assign to the heart and/or brain, medical examiners should take a proactive role in alerting families that these organs will be retained.

Third, families and next of kin should always be given the opportunity to acquire the retained organs for burial instead of the organs being destroyed. A key nuance to recognize is that there is a distinction between a property right in a decedent's body and a right of possession to the body. States have consistently recognized that the next of kin have a right to possession of the body for burial purposes. "[A] person who possesses anatomical specimens can only be challenged by 'a person with a better right to possession.'"[224] Under this theory, the people with the "best" right of possession are the families and friends who wish to bury the body properly.[225] Consequently, it is irrelevant whether the next of kin have a property interest in the body. Regardless of whether they have such a right, the next of kin will always have the "best" right of possession to the body. Therefore, Courts should recognize this right and require the return of major body organs.

The death of a loved one is one of the hardest things family and friends have to go through in life. People are entitled to get back whatever organs were taken from the body because the organs may have religious and cultural significance and family members may suffer emotional harm if they discovered that they buried their loved one partially intact. This harm can never be corrected if the organs have already been incinerated.

Lastly, and perhaps most compelling, is that by failing to fully inform families about organs retained during autopsies and denying them the ability to get the organs back, medical examiners are disrespecting the religious beliefs of many people. The failure to notify families about organs retained during an autopsy leads families to believe that they are burying their loved one in compliance with their religion or culture when, in reality, they are not. In order to sufficiently protect the rights of individuals regarding their religious and cultural beliefs, each state should require that families be given notice when the heart and/or brains are going to be retained, and the opportunity to re-acquire the retained organs for burial.

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179. *Id.*; *see* MISS. CODE ANN. § 41-39-1 (West 2013).

180. Miss. Code Ann. § 41-39-1 (West 2013).
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186. *Id.*
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188. Klaiman, *supra* note 131, at 482.
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Mental Health Reform: Predicting Suicide, but Then What?

By Michelle Frankel

I. Introduction

If asked to rank the biggest problems faced by teenagers, most adults would not list suicide.[1] Yet, the Centers for Disease Control (CDC) determined that suicide is the third leading cause of death "for youth between the ages of 10 and 24."[2] Approximately 157,000 young adults in this age group attempt suicide each year.[3] While most young adults do not actually die from these attempts, the large number demonstrates that teen suicide risk is a serious problem.

CDC statistics indicate that suicide is a prominent issue in the U.S., ranking among the top 10 leading causes of death.[4] Suicide accounts for about 38,364 deaths per year,[5] and suicide attempts result in a yearly average of 713,000 emergency department visits for self-inflicted injuries.[6] Of those who commit suicide, more than 90% have a diagnosable mental disorder.[7]

Mental illness is also a major problem in the U.S. About 57.7 million Americans over the age of eighteen have a mental disorder,[8] and "half of all lifetime cases of mental disorders begin by age 14."[9] By comparison, other disorders, such as Alzheimer's and diabetes, affect 5.2 million Americans[10] and 25.8 million children and adults,[11] respectively.

Given these statistics, mental illness should be a higher priority and receive more national attention. Americans should be screened for mental illness and suicide risk, as they are for other disorders that affect millions of people. Unfortunately at the present time, mental disorders and suicide are so stigmatized that there is a disparity in mental and physical health treatments.

This article will address the recent discovery of biomarkers that can potentially detect suicide risk and focus on how such biomarkers could be instrumental in preventing suicide if used in collaboration with changing the current approach to mental health care.

II. Overall Need to Reduce the Stigma Associated with Mental Illness and Suicide

It seems impossible to effectively address the prevalence of mental illness, or more specifically suicide, without first reducing the stigma. Individuals with mental illness must feel equally free to seek mental and physical health care, but unfortunately that is not the case. Larry M. Lake wrote about the contrasting reaction of his community members when his wife was diagnosed with breast cancer and when his daughter was diagnosed with bi-polar disorder; friends constantly brought over food and offered to help when his wife underwent treatment, but hardly anyone did that after his daughter was diagnosed.[12] Lake commented that,

> Friends talk about cancer and other physical maladies more easily than about psychological afflictions. Breasts might draw blushes, but brains are unmentionable. These questions are rarely heard: How's your depression these days? What improvements do you notice now that you have treatment for your ADD? Do you find your manic episodes are less intense now that you are on medication? What does depression feel like? Is the counseling helpful?[13]

Thus, there is a need for "mental health parity," meaning that "issues such as depression or schizophrenia would be treated for as long as necessary, much as a broken arm is treated until it is healed, rather than having limits on allowed visits per year or insurance policies that don't include mental health at all."[14] This change would reduce discriminatory behavior toward the mentally ill and foster treatment that endures post-hospitalization.

The passage of the Affordable Care Act (ACA) represents the most recent legislative action emphasizing the importance of mental health parity. Reacting to the fact that 25 percent of the 47.5 million uninsured Americans have a mental health condition, the ACA builds on the federal Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) by requiring that all "health insurance plans on the Health Insurance Marketplaces cover mental health [] services."[15] Insurance companies will no longer be able to use discriminatory medical management to deny coverage for certain mental health treatments,[16] and will be required to "cover preventive services like depression screening [] and behavioral assessments [] at no cost."[17] These newfound efforts are critical because they will promote early detection and intervention, which can reduce the prevalence of mental illness, including suicide, by as much as 50 percent.[18]

III. Genetic Testing for Suicide Biomarkers—A New Way to Assess Suicide Risk

Recognizing that people who intend to commit suicide may not express their feelings or seek assistance, Dr. Alexander Niculescu, an associate professor of psychiatry and medical neuroscience at the Indiana University School of Medicine, spearheaded a study of men with bipolar disorder to search for biomarkers that might indicate

higher risk of suicide.[19] Dr. Niculescu and his colleagues identified 6 biomarkers that they were "reasonably confident [were] indicative of suicide risk,"[20] and then they examined the biomarkers to determine if they could predict suicide hospitalizations.[21] Their discovery is pivotal because it demonstrates the presence of "trait markers," which highlight the behavioral and biological processes that may play a causal role in the development of a psychiatric disorder, AND "state markers," which refer to the actual manifestation of the disorder in patients.[22]

Despite the small sample size of this study, the biomarker discovery represents a milestone in understanding suicide risk because it "opens a window into the biology of what's happening,"[23] which may transform our general understanding. Pointedly, the researchers' ability to predict hospitalization increased from 65 to 80% when Dr. Niculescu's biomarkers were used along with other clinical measures of mood and mental state.[24] The hope is that these biomarkers will become increasingly accurate in predicting suicide risk, but for purposes of this article, it will be *assumed* that the identification of suicide biomarkers can definitively predict individual risk of suicide. Unfortunately, this study must be replicated on a larger scale before suicide biomarker screening can be used effectively as a mainstream method to assess suicide risk.

IV. Using Biomarkers to Identify Individuals Who May Be at Risk of Committing or Attempting Suicide

The traditional approach to identifying people at risk of committing or attempting suicide involves providing mental health services to those who proclaim or show signs of suicidal thoughts or behaviors.[25] While it is imperative to continue helping such individuals, the sheer number of attempted and actual suicides demonstrates that many "at-risk" people are not being discovered or treated, so other indicators of mental illness and/or suicide risk must be utilized.

Testing for genetic biomarkers may allow psychologists to screen and treat individuals who fall into "high-risk" groups but are not discovered by the traditional approach. Behaviors that are commonly associated with an increased suicide risk include diagnosed mental disorders,[26] family history of depression,[27] or exposure to parental psychiatric illness.[28] There is a strong association between psychotic experiences, such as paranoia and delusions like hearing voices, and suicide attempts too.[29] One study of psychopathology found that experiencing psychotic symptoms nearly *tripled* the chance of suicide: "34% of those experiencing psychotic symptoms *plus* other types of psychopathology made a suicide attempt… [and] only 13% of those experiencing psychopathology *without* psychotic symptoms made such an attempt."[30]

Individuals who have been exposed to adversity, such as family turmoil, alcohol and substance abuse, and domestic violence, may also have an increased risk of suicide.[31] Teenagers in particular may be impacted by failure, breakups, and bullying as well.[32] It is essential to begin using these risk factors to identify individuals who should receive mental health treatment because asking if someone is "struggling with anxiety or depression, or [has] thoughts about harming himself or others,"[33] may not always lead to an admission.

Nonetheless, assessing these signs and experiences can be subjective, so they must be approached in a way that is as objective and non-judgmental as possible. The development of objective methods of identifying mental health risk, such as screening for suicide biomarkers, can be used in collaboration with an assessment of individuals' other non-genetic risk factors to better identify individuals with a high suicide risk.

V. Implementing Genetic Testing for Suicide Biomarkers Through Public Schools to Address the Rate of Teen Suicide

A. Why to Test Teenagers Through Public Schools

Testing teenagers for suicide biomarkers may enable psychiatrists to find high-risk individuals earlier, which will facilitate better treatment. Screening teenagers is a valid starting point because being a teenager alone increases the risk of suicide starting at age 14.[34] Also, since students spend most of their childhood attending school, school officials are in a good position to address suicide because they often play an active and important role in students' lives.[35]

However, school programs to screen for suicide biomarkers may raise a few constitutional issues if they are administered discriminatorily or infringe on the privacy rights of students. All teenagers in public schools can be tested to avoid discrimination. Privacy issues can be avoided because schools have the historic authority to address severe public health and safety concerns,[36] including the prevalence of teen suicide, and to mandate annual physical examinations of all attending students.[37] Still, schools should follow judicially reviewed frameworks for mandatory drug testing to further ensure that suicide biomarker screening programs do not unconstitutionally infringe on students privacy rights.

B. How to Test Teenagers for Suicide Biomarkers Through Public Schools—Using Drug-Testing Programs as a Constitutional Framework

Schools can ensure the development of constitutionally valid programs that mandate suicide biomarker screening by following judicially approved drug testing initiatives. When instituting such programs, schools must be careful to avoid violating the Fourth Amendment,

which prohibits federal and state officers from performing unreasonable search and seizures.[38]

Generally, the Supreme Court determines the constitutionality of a search by assessing its "reasonableness," which involves "balancing its intrusion on the individual's Fourth Amendment interests against its promotion of legitimate governmental interests."[39] The Fourth Amendment does not require individualized suspicion for a search and seizure to be constitutional;[40] rather, the Supreme Court has upheld suspicion-less searches when drug testing railroad employees and customs officers given the diminished expectation of privacy in such heavily regulated industries and the strong government interest in promoting public safety.[41] New York courts assess the reasonableness of suspicion-less searches similarly, and have only deemed such searches to be reasonable "when the privacy interests implicated are minimal, the government's interest is substantial, and safeguards are provided to insure that [] individual[s'] reasonable expectation of privacy is not subjected to unregulated discretion."[42]

School-mandated suspicion-less suicide biomarker screening programs might be constitutional if schools consider guidelines highlighted in drug testing cases including: (1) the nature of the privacy interest(s) involved, (2) the character of the intrusion, namely the manner of specimen collection and the limited nature of the testing and disclosure results, and (3) the "nature and immediacy of the governmental concern."[43] Schools must balance the nature of students' privacy interest against the intrusiveness of urine analyses to detect suicide biomarkers given the national and state interests in addressing the prevalence of teenage suicide.

The Supreme Court and N.Y. Court of Appeals have held that the custodial relationship between public school authorities and students creates a diminished expectation of privacy in the school environment,[44] and so the "basis for finding sufficient cause for a school search will be less than that required outside the school precinct."[45] The fact that students are "statutorily required to undergo [annual] physical examination[s]"[46] diminishes student expectations of privacy too. Consequently, even though students have a legitimate privacy interest in the "revealing information" that can be obtained from urine samples,[47] it may be reasonable to mandate suicide biomarker screenings as part of annual physical examinations, which typically involve vision, hearing, and blood screenings.[48] Such school mandated screenings are "accepted and traditional"[49] and suicide biomarkers can be added as "just another layer."[50]

Procedural safeguards can further ensure that "each [student] retains important personal rights of privacy,"[51] while allowing the government to use suicide biomarker screening to begin addressing the prevalence of suicide among teenagers. Urine specimens should only be tested for *suicide* biomarkers after being collected as they normally are in doctors' offices.[52] Screening results should only be disclosed to parents, one school employee (tasked with ensuring that counseling is provided), and the student him or herself (if there is parental approval because knowing such information may do more harm than good by impacting anxiety, self-esteem, and/or optimism).[53] The results should not be disclosed to more individuals unless a student exhibits clear signs of imminent suicide risk, or a student's parents have decided to start a treatment regimen that requires awareness and involvement by more school officials. Still, it may be instrumental to have one school employee cognizant of a students' positive result because faculty members are more likely to be objective than parents and can observe students on their own school turf, where they feel more comfortable.[54] School employees can be trained to provide counseling and support for students too.[55] Law enforcement officials should not be notified of the results,[56] and administrators should not use them punitively.[57]

The "balancing of [] personal rights against [this] urgent social necessit[y]" leans in favor of instituting suicide biomarker screening programs within public schools,[58] because "the school is a special kind of place in which serious and dangerous [circumstances including epidemic dangers such as the predominance of teen suicide are] intolerable…[and] may not be ignored." States have a compelling interest[59] in diminishing teen suicide because it is a particular "problem among [teenagers] generally,"[60] and impacts individual teens, their family and friends.[61] Once perfected, knowing a student's biological disposition to suicide can promote early intervention, the benefits of which are profound,[62] and may be a key part of a multifaceted approach to combating teen suicide. Still, the benefits will be minimal if there are no programs available to help individuals cope with the results and address their risk.

VI. Using Genetic Testing in Collaboration with Other New Treatment Programs to Reduce Suicide Risk and Mental Illness

A. Reducing the Stigma by Changing the Overall Approach to Mental Health Treatment

The recent ACA mandate of mental health parity promotes using a similar treatment approach for physical and mental illnesses and making larger scale changes to mental health treatment. A public health approach can be used to prevent suicide and would involve focusing "on prevention [efforts] that impact groups or populations of people, versus treatment of individuals,"[63] which would be advantageous since suicide is so widespread throughout the population. This approach would reverse the traditional view of "treat[ing] the disorder and [then] the

suicidality…"[64] by focusing on primary prevention: the "prevent[ion of] suicidal behavior before it occurs, and address[ing] a broad range of risk [] factors."[65] This approach would also emphasize increasing scientific understanding,[66] which may be achieved if professionals, and particularly researchers, share their ideas and discoveries more frequently and "galvanize [their research] to further develop and consolidate knowledge."[67]

Finally, a public health approach would foster multi-disciplinary collaboration between those who identify suicide risk and those who treat it, thereby unifying the currently scattered efforts to treat mentally ill patients. A multi-disciplinary approach requires "a psychiatrist [to be] a member of, not a consultant to, the team, [and to make] the [patient] a client of the team [as a whole], not of an individual staff member,"[68] compared to the traditional linkage case-management approach which "connects [mentally ill patients] to services provided by multiple mental health, housing, and rehabilitation agencies or programs," and creates a group of *individual* case managers, each of whom is responsible only for his or her own caseload.[69]

Programs that involve multi-disciplinary collaboration have started to be implemented. The National Alliance on Mental Illness (NAMI) created a Program of Assertive Community Treatment (PACT), which provides outpatient treatment to mentally ill patients whose needs have not been, or cannot be, met adequately using the traditional approach.[70] PACT provides a round-the-clock, multi-disciplinary psychiatric unit, consisting of a combination of psychiatrists, social workers, nurses, and rehabilitation workers, to treat individuals with "severe and persistent mental illness causing [] impairments that produce distress and major disability in adult functioning (e.g., employment, self-care, and social and interpersonal relationships)."[71] Even though round-the-clock outpatient care may not be necessary for all mentally ill patients, collaboration should be promoted or mandated because without it patients, who often already have difficulty fulfilling their daily functions, are primarily responsible for coordinating their own care. Professional collaboration may also ensure that treatment regimens remain effective while patients live within the community (as opposed to in an institution) because "the gains made by [patients] in the hospital [are] often lost when they move[] back into the community."[72]

As the mental health treatment approach is changed, there must also be efforts to better identify mentally ill or suicidal patients because many individuals are uncomfortable sharing their feelings and/or unable to pinpoint what is causing grief. To get patients to open up more, medical professionals should increase engagement by using methods such as the Suicide Status Form (SSF). The SSF enables the patient to become an "expert on his/her own case" by having the therapist sit next to the patient as he/she fills out a questionnaire, and it helps therapists determine what drives a patient's suicide risk because "you're not preaching to the patient and not leaving it to [him/her] to figure out what the problem is, [rather] you're working together."[73] More objective approaches should be developed and used to learn about individuals' feelings and to create an environment where individuals are more willing and likely to seek treatment.

B. Ensuring the Effective Institution of Screening Programs Through Schools by Simultaneously Developing Programs to Raise Awareness About Mental Illness

Implementing screening programs, like the one for suicide biomarkers, may raise societal awareness and begin to reduce mental illness' stigma, but schools should still start to educate students and adults about mental health. Schools can do this rather easily by hosting assemblies and essay or art contests. School-based assemblies have one of the largest impacts on raising "awareness, understanding, and tolerance of mental health issues," and are rather simple and inexpensive to institute.[74] They foster interactive non-threatening discussions among faculty and students, educate large groups, and popularize ways to recognize mental illness and how/where to get help. Essay and art contests with topics such as "what does mental health mean to you?" and "what are positive strategies I can use when I am upset?"[75] can raise awareness too, and they can be adapted to suit different age groups; younger students can be offered coloring contests or asked to act out different feelings, and older students can be asked to develop classroom lessons or make a video.[76] Mental illness may become less taboo by educating students and faculty, and interactively incorporating mental health information into school activities.

C. Broadening the Scope of Programs That Raise Awareness About Mental Illness

Programs instituted through public schools can educate parents and faculty. Parents can voluntarily attend school assemblies or be required to do so once per academic year. Parents can also learn about mental health by hosting speakers at PTA meetings, mailing fact sheets, and sending out automated messages.[77] It would be particularly advantageous to offer programs like the Learning to Live (L2L) program, which is offered in Chicago.[78]

> [The program] offers a "10 days in 10 weeks" curriculum designed to educate health professionals, law enforcement officers, teachers, counselors, school staff, parents and students about 13 mental health disorders common in adolescents including suicide, depression, self-mutilation, anxiety, and eating disorders.[79]

Programs like L2L should be used in more, if not all, schools because such programs are a relatively quick and inexpensive way to educate a wide range of people about the most pressing mental health issues.

Moreover, the Mental Health Association of Greater Chicago (MHAGC) educates parents and teachers by offering them a "partnership" program, which includes classes to "facilitate[] discussion[s] [about] the source of problems, how to resolve them, and how to effectively interact with adolescents [and children] ages 6-18."[80] It helps parents build confidence about dealing with mentally ill children and provides them with step-by-step ways "to shift negative emotions into positive ones."[81] This program can address teen suicide risk by educating individuals involved in teenagers' daily lives about warning signs and how to help.

Once school faculty members are better educated, they can incorporate mental health exercises into the daily curriculum. They can perform "Cross the Line" exercises during state-mandated physical education and/or health classes,[82] and have all students stand on one side of a line until they can answer "yes" to a question.[83] It may be advantageous, if not imperative, to ask non-personal questions so that students are more inclined to answer honestly. Such questions may include: Do you know anyone who suffers from mental illness, cries or is sad a lot, has been bullied, or has recently broken up with a boy/girlfriend? This exercise will enable the faculty to raise a wide-array of issues and to show students that other classmates face similar experiences.

Online resources are an effective method of providing easy access to mental health treatment because such forums can target specific age groups. The American Foundation for Suicide Prevention developed the Interactive Screening Program (ISP), which has effectively drawn out students at risk of suicide by enabling them to anonymously interact with professionals.[84] Such anonymity is a key feature of some online forums and makes them enticing to individuals apprehensive about seeking treatment.

Social forums, such as Facebook, Twitter, and YouTube, are expanding as mental health and suicide treatment mediums and may be instrumental in reaching certain age groups, especially teenagers.[85] Other technological advances are broadening treatment options and can help professionals reach more people. Cell phone applications are also being developed to educate individuals about signs of mental illness. The Electronic Preventive Services Selector (EPSS) application allows psychiatrists to "type in a patient's demographic information, and [receive] evidence-based screening tools….to help detect early warning signs of a mental disorder." [86] Even though such technological advances should be used skeptically until they are proven to be effective, they can have a big impact on the mental health world one day.

Thus, reforms to mental health care are necessary to combat mental illness and suicide. Increasing the number of *non-medical* eyes that can identify people suffering from mental illness or suicide risk can profoundly impact our ability to diminish the prevalence of mental illness.

VII. Conclusion

When instituting the new approaches and programs mentioned above, it is imperative to remember that changes within the mental health system will take time. However, even an increased awareness can have an immense impact on the prevalence of mental illness and suicide risk, as proven by the history of raising awareness about HIV and smoking. Both campaigns, which involved large-scale prevention efforts, took years to be effective, but ultimately led to a reduction in their prevalence.

> [L]arge-scale prevention programs [like the anti-smoking campaign] eventually reduced the number of smokers significantly. Of course, it may be argued that suicidal thoughts and behavior differ from lighting a cigarette, [that] does not mean that [the societal prevention] approach cannot be taken. Efforts to improve knowledge, attitudes, and help-seeking behavior are being made in middle and high schools, and they seem to have yielded results as far as knowledge and attitudes are concerned. It is too early to conclude that such efforts prevent suicide, but we should not forget that it took some time before anti-smoking campaigns produced an effect.[87]

Thus, in a perfect world, "the prevalence of adversities that drive human vulnerabilities toward distress and disease [could simply be eliminated, while] at the same time increas[ing] people's willingness to grab a helping hand."[88] For better or for worse, such a utopia is impossible to attain. And so, as the world remains imperfect and fosters an abundance of mental illness and suicide, there is nothing left to do but focus on what *can* be perfected: our ability to treat and cope with such illnesses.

Screening for suicide biomarkers will help achieve these goals by creating an objective means to assess individuals' suicide risk. The current prevalence of suicidal acts and/or attempts indicates that new approaches to identifying "at risk" individuals must be developed in collaboration with new treatment programs, and most importantly, with efforts to make mental illness less taboo.

Endnotes

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Michelle Frankel is a third-year law student at Albany Law School. She is an advocate of systematic health care reform with an interest and focus on corporate and policy issues.

NEWS flash

What's Happening in the Section

Margaret (Margie) J. Davino

Margie Davino took office as Chair of the Health Law Section on June 1, 2014. Margie is a partner in Kaufman, Borgeest and Ryan, LLP, and practices in the firm's office at 120 Broadway, NYC. Her practice focuses on health care law, including transactional, compliance, contractual, corporate, regulatory and risk management legal issues. Previously, she served as General Counsel of St. Vincent's Hospital and Medical Center of New York and General Counsel of St. Joseph's Hospital and Medical Center in Paterson, New Jersey. Margie holds a J.D. from Vanderbilt University School of Law, and an MBA from Seton Hall University.

Officers

The other Section officers who took office on June 1 are:

Chair-Elect:	Kenneth R. Larywon Martin, Clearwater & Bell (NYC)
Vice-Chair:	Raul A. Tabora, Jr. Bond Schoeneck & King, PLLC (Albany)
Secretary:	Lawrence Faulkner ARC of Westchester (Hawthorne)
Treasurer:	Robert A. Hussar Manatt Phelps & Phillips (Albany)

Committee Activities

- **The Public Health Committee** launched on June 27, 2014 the first session in its webinar series "A Look at Public Health Mandates and Public Health Legislation: Hot Topics in Public Health Law and Public Health Ethics." This first session addressed tobacco legislation through an overview of New York City's tobacco control laws. The featured speakers were Committee member Thomas Merrill, General Counsel, and Kevin Schroth, Senior Legal Counsel, with the New York City Department of Health and Mental Hygiene.

The second session of the webinar series was "Crisis Standards of Care: Public Health Ethics in Light of Evolving Mandates," featuring Daniel Orenstein, J.D., Deputy Director, Network for Public Health Law Western Region, Fellow and Adjunct Professor of Law, Public Health Law and Policy Program, Sandra Day O'Connor College of Law at Arizona State University on Friday, September 26, 2014.

The third and final session features Lawrence O. Gostin, University Professor and Founding O'Neill Chair in "Global Health Law," Georgetown University. Professor Gostin will discuss his recent book *Global Health Law* (Harvard University Press, 2014). The third session is Thursday, December 11, 2014, 4 pm-5 pm Eastern Standard Time. The Public Health Committee is pleased to sponsor this webinar series with the support and collaboration of the Network for Public Health Law. To register for the December 11, 2014 webinar, please send an email to jrose@networkforphl.org. CLE is available for these webinars upon request.

In addition to the webinar series, which is available nationwide through the Network for Public Health Law's platform, the Public Health Committee is continuing with its conference call member meetings featuring informational speakers. The latest call, on August 6, 2014, featured background materials and information on New York's new medical marijuana law courtesy of Noah Potter, Esq.

The Public Health Committee is also assisting New York State public health authorities in emergency preparedness planning related to potential Ebola scenarios. We are coordinating availability of volunteer health law attorneys to provide assistance or representation in hearings on quarantines or other public health directives. If you are interested in learning more about assisting in this manner, please contact Julia Goings-Perrot, Chair of the Public Health Committee, at jgoings-perrot@cmmrlegal.com.

- **The E-Health and Information Systems Committee** has established a Telehealth Workgroup to develop an online professional resource to open a dialog among stakeholders in the area of telehealth/telemedicine. The Workgroup has also initiated a Student Internship Program with Albany Law School to research and post findings to the online resource concerning terminology, reimbursement, licensure and other provider issues related to adoption of telehealth/telemedicine.

  The Committee held a CLE on May 15, 2014 in New York City with speakers from the Legislature, Department of Health and private practice to discuss the history of telehealth/telemedicine, regulatory trends and legislative initiatives, as well as introduce the Telehealth Workgroup.

  The Committee also held a CLE on September 17, 2014 at Albany Law School with speakers from state administrative agencies, health care provider associations and private practice to discuss advancements and barriers to adoption of telehealth/telemedicine with a focus on licensure and reimbursement issues.

  For more information, contact Charles C. Dunham IV, dunhamc@bsk.com.

Program Integrity and Enforcement: The Government Perspective Program: (left to right) Jay Speers, Robert Hussa and James Sheehan

Recent Events

- **Program Integrity and Enforcement: The Government Perspective.** This program, co-sponsored by the New York City Bar Health Law Committee, was held on September 12, 2014 at the Yale Club in NYC. The program presented an opportunity for health lawyers to meet and hear from four United States Attorneys as well as representatives from the New York State Attorney General's Office and the New York State Office of the Medicaid Inspector General.

- **Telehealth & Telemedicine: Progress and Barriers in New York.** This program was held on September 17 at Albany Law School, and webcast to other locations. It is the second in a series looking at telehealth and telemedicine in New York State, exploring the progress made towards the adoption of telehealth and telemedicine services in New York State, New York's legislation regarding this area, and the legal barriers to be overcome. Program Chair: Charles C. Dunham, IV, Esq., Bond Schoeneck & King, Albany, NY.

- **Crisis Standards of Care: Public Health Ethics in Light of Evolving Mandates.** Held on September 26, 2014, this was the second webinar in a series, "A Look at Public Health Mandates and Public Health Legislation: Hot Topics in Public Health Law and Public Health Ethics." The speaker was Daniel Orenstein, JD, Deputy Director, Network for Public Health Law Western Region, Fellow and Adjunct Professor of Law, Public Health Law and Policy Program, Sandra Day O'Connor College of Law at Arizona State University.

- **Health Care Delivery System and Payment Reform in New York State**. This event was held on Friday, October 24, 2014 at the State Bar Center in Albany
  The Fall Meeting provided an unprecedented opportunity to discuss the implications of federal, state and other initiatives on the organization of health care delivery in New York State and the strategies that health care lawyers are developing to address the related legal issues and challenges.

  The Fall Meeting brought together leading attorneys, policymakers, experts, and implementers to provide unique and in-depth insights on these ongoing delivery system and payment reforms. The

Program Integrity and Enforcement: The Government Perspective Program: (left to right) Richard Hayes, Winston Paes, Jonathan Cohen, Rebecca Martin and Robert Borsody

Meeting covered a variety of topics including New York's Delivery System Reform Incentive Program (DSRIP), accountable care organizations (ACOs), innovative contract and payment arrangements, and related legal issues.

Further information about upcoming programs is available at www.nysba.org/health.

- **The New York State Bar Association 2015 Annual Meeting**
  Health Law Section Program
  January 28, 2015
  New York Hilton Midtown
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  New York City
  www.nysba.org

  More information to come. Save the date!

Section Committees and Chairs

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

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