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:
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> 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/).
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> 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.
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> **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.
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> 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.
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> 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.**