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Health Law UPDATE

April 2019

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FEDERAL UPDATE

CMS Implements Opioid Policies for Intervention at the Pharmacy Level

Centers for Medicare & Medicaid Services (CMS) recently sent letters to health care providers explaining its new pharmacy alert polices. These letters are part of joint efforts by CMS and the U.S. Department of Health & Human Services (HHS) to combat the overuse and over-prescription of opioids.

Effective January 1, 2019, Medicare drug plans began employing safety alerts at the pharmacy level, which involved the implementation of seven-day supply limits for patients with initial opioid prescriptions and increased care coordination amongst pharmacies. Pharmacies filling initial opioid prescriptions for patients are only authorized to fill a seven-day supply unless the prescribing physician contacts the drug plan for an override or until the prescriber writes an additional prescription. The additional opioid prescription would make the patient no longer a "naïve" opioid user, and thus, no longer subject to this seven-day supply limitation. Further, increased care coordination will be employed to provide pharmacists with alerts when a patient's cumulative morphine milligram equivalents prescription reaches 90 mg. To proceed with filling the prescription once the patient is at this 90 mg. limit, the pharmacy may call the prescribing provider to confirm the patient's medical necessity for the high dosage.

In these letters, the CMS directs providers to review and implement alternative treatment plans for pain. The letters also direct providers to the HHS's published guidance document promoting the use of the drug Naloxone to treat patients at risk for opioid overdose. According to CMS's recently published roadmap, the CMS's and HHS's concerted efforts already have resulted in a great deal of success

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Jocelyn Ezratty | 973.364.5211 | jezratty@bracheichler.com

Adverse Events Prompt FDA to Issue Warning about Use of Surgical Staplers and Staples

On March 8, 2019, the United States Food & Drug Administration (FDA) issued recommendations regarding the use of surgical staplers and staples for internal use to reduce the risk of adverse events.

From January 1, 2011 to March 31, 2018, the FDA received over 41,000 medical device reports (MDRs) related to surgical staplers and staples for internal use. The MDRs disclosed adverse events and product problems, which included 366 deaths, over 9,000 serious injuries, and more than 30,000 malfunctions.

The FDA advised that stapler malfunctions and misuse can result in bleeding, sepsis, tearing of internal tissues and organs, increased risk of cancer recurrence, and death.

To improve patient outcomes, the FDA recommends:

- Carefully reading and following the manufacturer's instructions
- Having a range of staple sizes available and selecting the appropriate size cartridge for tissue type and thickness
- Avoiding using staples on large blood vessels like the aorta
- Avoiding clamping a stapler on delicate tissue, which can cause injury even if no staples are fired

In addition, the FDA instructs providers in management of a malfunction while applying staples across a blood vessel.

Draft guidance with labeling recommendations for manufacturers is expected in the next few months. The FDA is also contemplating changing the classification of surgical staplers, which could enable performance testing and special labeling.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

Rules Proposed to Improve Access to Electronic Health Information

On March 05, 2019, 13 members of the United States Senate wrote a letter to the Secretary of the U.S. Department of Health & Human Services (HHS) in which the Senators urged the Secretary to initiate the rulemaking process regarding the Confidentiality of Alcohol and Drug Abuse Patient Records known as 42 CFR Part 2. This section of the Code of Federal Regulations limits the use and disclosure of patient records and identifying information from substance use disorder treatment programs. In accordance with 42 CFR Part 2, medical professionals may not be able to access a patient's entire medical record. This prevents medical professionals from understanding the full scope of a patient's condition which may result in a physician making a medical decision without fully understanding the ramifications of the physician's decision.

The House of Representatives passed bipartisan legislation, the Overdose Prevention and Patient Safety Act (the Act), which prevents the misuse of addiction records. For example, the legislation would prevent the use of addiction records in criminal, civil, or administrative proceedings and penalizes those who misuse a patient's substance abuse record. The Act also contains provisions to permit disclosure of substance abuse records without written consent from patients

in accordance with HIPAA. The goal of new legislation is to update regulations so that regulations and modern medicine may continue to develop and maintain safe treatment for patients.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

Federal Appeals Court Rules That Wife Can be Liable for Medicare Fraud at Husband's Health Care Company

The federal Third Circuit Court of Appeals ruled in a written opinion dated March 14, 2019, that a woman convicted of Medicare fraud for unsupervised neurological testing at a company owned by her husband could also be liable in a civil whistleblower lawsuit even though she did not have an ownership interest in the company.

Nita K. Patel and her husband, Kirtish N. Patel, had both pled guilty to criminal charges in November 2015 for schemes to defraud Medicare. With regard to one of the schemes, Ms. Patel admitted in her guilty plea that she falsely represented to Medicare that the neurological testing performed at Biosound Medical Services, her husband's diagnostic company, was supervised by a licensed neurologist, when, in fact, it was not. A whistleblower lawsuit by a former Biosound employee had also been filed against the Patels for, among other claims, violations of the False Claims Act (31 U.S.C. § 3729(a)(1)(A) and (B)) in connection with the same Medicare fraud schemes. A federal district court found Ms. Patel liable for the False Claims Act violations based on her guilty plea statement in the criminal action.

Ms. Patel appealed the district court's judgment against her, arguing that she could not be liable for False Claims Act violations because she was only an employee of her husband's company. She claimed that she had no duty to ensure that Biosound employed a supervising neurologist and that she was not in charge of ensuring Biosound's compliance with Medicare regulations. The Court of Appeals rejected Ms. Patel's arguments, ruling that ownership interest is irrelevant to liability under the False Claims Act. The court explained that while False Claims Act violations are typically brought against corporations and their executives and board members, "individuals at all levels of a company have been found liable under the FCA."

This case serves as a cautionary tale that individual, non-owner employees may be found liable under the False Claims Act.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

OIG Advises Regarding Risks of Providing Free In-Home Care

In a recently published Advisory Opinion, the U.S. Department of Health & Human Services, Office of the Inspector General (OIG) determined that it would not impose sanctions under either the Civil Monetary Penalties (CMP) law or the federal Anti-Kickback Statute (AKS) in connection with a proposed arrangement wherein a hospital would provide free in-home, post-discharge support to patients. Under the proposed arrangement, a hospital would offer free in-home, follow-up services to certain patients with the goal of ensuring patient compliance with discharge plans, improving patient health, and reducing hospital admissions and readmissions. The program would be limited to patients who have a current or recent inpatient admission who have been identified to be at high risk for readmission, who have scheduled follow-up care at the hospital, and who live within the hospital's service area, without regard to the patient's insurance carrier or ability to pay. The in-home services would be provided by a hospital-employed paramedic who would visit the patient twice per week to monitor the patient's compliance with discharge plans, inspect home safety, and evaluate the need for follow-up care, regardless of who will provide that follow-up care.

The OIG determined that while the proposed arrangement is suspect under the CMP law and the AKS, the benefits of the program outweigh the potential for patient steering. The OIG determined that the risk of influencing patients to select the hospital to provide other services would be negligible because only patients who had already chosen the hospital for follow-up care would be eligible for the program, and patients would be free to choose any provider for other unrelated services. In addition, the services provided through the program would not be reimbursed by federal health care programs, and therefore the program would be unlikely to increase costs to federal health care programs. Additionally, if the program is successful, the result would be an overall savings due to improved health and reduced unnecessary inpatient admissions. The OIG also considered that the program would be unlikely to skew clinical decision making.

The OIG opined that the proposed arrangement would not qualify for the "promotes access to care" exception to the CMP law, citing previous OIG commentary that in-home, follow-up care in general is not necessarily proven to prevent the patient from requiring follow-up care. The OIG determined, however, that it would not subject this particular arrangement to administrative sanctions because the arrangement's potential benefits outweigh any risk of inappropriate patient steering. However, given the OIG's reliance upon the specific details of the particular arrangement in making its determination, it remains unclear whether other providers who provide similar services can rely on the OIG's decision in this Advisory Opinion.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

Identifying Immediate Jeopardy Under Medicare Manual Revised Appendix Q

On March 5, 2019, CMS issued a Quality, Safety & Oversight Group Memo concerning revisions to Appendix Q of the Medicare State Operations Manual, providing revised guidance to surveyors relating to "immediate jeopardy" circumstances for all providers and suppliers, including hospitals, clinical laboratories, and long-term care facilities. The revisions are effective immediately. The revised Appendix Q creates a Core Appendix Q that will be used by surveyors in determining whether an immediate jeopardy is present, which is defined by CMS as "a situation in which a recipient of care has suffered or is likely to suffer serious injury, harm, impairment, or death as a result of a provider's, supplier's, or laboratory's noncompliance with one or more health and safety requirements." CMS included with the revisions an Immediate Jeopardy Template, which will assist with communication and efficiency between surveyors and those issued a citation for immediate jeopardy.

To cite a facility for immediate jeopardy, a surveyor must determine the following: "(1) noncompliance (2) caused or created a likelihood that serious injury, harm, impairment or death would occur or reoccur; and (3) immediate action is necessary to prevent the occurrence or recurrence

of serious injury, harm, impairment or death to one or more recipients." In addition to the template, CMS has provided a training tutorial for Core Appendix Q to better enable providers, suppliers, surveyors, management staff, and laboratories to identity instances of immediate jeopardy.

Among the key changes set forth in Core Appendix Q is the change in item 2 above, from "potential" for harm to "likelihood" of harm, and in item 1 above, replacement of the requirement that a surveyor find culpability with the requirement to simply demonstrate noncompliance. Specific instructions were given to surveyors regarding psychosocial harm, including that the surveyor is to use the standard of "reasonable person" in determining whether "noncompliance caused or made likely serious mental or psychosocial harm to recipients." Also, CMS drafted specific subparts for concerns of immediate jeopardy in nursing homes and clinical laboratories.

In addition, each citation for immediate jeopardy must be considered independently from each and every other citation and there is no instance in which a situation of immediate jeopardy will be given automatically without a surveyor determining that each element of the violation exists.

For more information, contact:

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Jocelyn Ezratty | 973.364.5211 | jezratty@bracheichler.com

STATE UPDATE

NJ Assisted Suicide Act Awaiting Governor's Signature

The New Jersey Medical Aid in Dying for the Terminally Ill Act is awaiting the signature of Governor Murphy. If signed into law, the act would recognize "New Jersey's long-standing commitment to individual dignity, informed consent, and the fundamental right of competent adults to make health care decisions about whether to have life-prolonging medical or surgical means or procedures provided, withheld, or withdrawn," and would affirm "the right of a qualified terminally ill patient, protected by appropriate safeguards, to obtain medication that the patient may choose to self-administer in order to bring about the patient's humane and dignified death."

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com

New Jersey Legislative Update

Bundled Payments for Childbirth-Related Services Advances in NJ – On March 4, 2019, the New Jersey Senate Health, Human Services and Senior Citizens Committee advanced Bill S3365, which would establish bundled payments for childbirth-related services. An identical bill had already been cleared by the New Jersey Assembly's Appropriations and Women and Children committees. The Bill will implement a three-year Medicaid perinatal episode of care pilot program, to be developed by the "perinatal episode of care learning network" established under the Bill. The learning network will design a perinatal episode of care payment model, also known as a bundle payment model, in which provider reimbursement is based on target total cost of care for services provided within a perinatal episode of care, rather than on individual services provided within the episode of care. The Bill defines a "perinatal episode of care" as all pregnancy-related care including prenatal care, labor and birth, and postpartum care provided to a mother and infant, beginning 40 weeks prior to the delivery and ending 60 days after the delivery of the infant. The purpose of the Bill is to improve perinatal healthcare outcomes and to reduce the cost of perinatal care.

Newborn Screening Bill Making Progress – On March 11, 2019, the New Jersey Assembly Women and Children Committee reported favorably on Bill S484, which would revise the New Jersey Department of Health's (DOH) newborn screening program. The Bill was already passed by the New Jersey Senate on January 31, 2019. The Bill revises New Jersey's newborn screening program for congenital disorders by requiring the Commissioner of Health to establish a Newborn Screening Advisory Review Committee, consisting of medical, hospital, and public health professionals, scientific experts, and consumer representatives. The Committee would be authorized to make recommendations on the disorders to be screened for by the DOH, as well as on screening technologies, treatment options, and educational and follow-up procedures, to be used in the newborn screening program.

Bill Introduced Requiring Health Benefit Coverage for Influenza Testing – On March 7, 2019, Bill S3571 was introduced in the New Jersey Senate requiring health benefits coverage for influenza testing. Specifically, health insurers (including health, hospital, and medical service corporations; commercial, individual, and group health insurers; health maintenance organizations; health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs; the State Health Benefits Program; and the School Employees' Health Benefits Program) would be required to provide coverage for expenses incurred in the use of rapid diagnostic testing to screen for influenza A and B virus infections.

For more information, contact:

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

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Brach Eichler In The News

Congratulations to Health Law attorneys **Shannon Carroll** and **Jonathan Walzman** who have been promoted to Counsel.

We are pleased to announce that **16 Brach Eichler attorneys** have been named 2019 New Jersey Super Lawyers and 10 have been named New Jersey Rising Stars.

South Florida Hospital News and Healthcare Report covered **Lani M. Dornfeld's** recent CHPC designation (Certified in Healthcare Privacy Compliance) by the Compliance Certification Board (CCB), an organization that has developed criteria to determine competence in the practice of compliance and ethics across various industries and specialty areas.

Lani Dornfeld writes about steps to take in the event of a data privacy or security breach in the current issue of *The Florida Home Care Connection*, the magazine of the Health Care Association of Florida.

Cannabis Law Co-Chairs **John D. Fanburg** and **Charles X. Gormally** offer their observations on New Jersey's proposed cannabis bill.

New Date! Our tenth annual New Jersey Healthcare Market Review (NJHMR) will be held on September 18 - September 19 at the Borgata in Atlantic City.

To view a full listing of recent news items and to read the articles mentioned above, please click here.

HIPAA CORNER

ONC Releases Summary of Comments for Draft Burdens Report; Comment Period for Rule Proposal Ends Soon

On March 26, 2019, the Office of the National Coordinator for Health Information Technology (ONC) released public comments to submissions it received for its report, *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.* According to ONC, the "draft strategy focused on 4 areas: clinical documentation, health IT usability and the user experience, EHR reporting, and public health reporting. Many stakeholders commented on more than one focus area in their submissions, with the majority of submissions commenting on health IT usability and the user experience."

By way of background, in the 21st Century Cures Act (Act), Congress identified the importance of easing regulatory and administrative burdens associated with the use of electronic health records (EHRs) and health information technology (HIT). Congress directed the U.S. Department of Health & Human Services (HHS) to establish a goal, develop a strategy, and provide recommendations to reduce EHR-related burdens that affect care delivery. The draft report reflected input HHS received through various listening sessions, written input, and stakeholder outreach.

On March 4, 2019, ONC and HHS published a proposed rule to implement certain provisions of the Act, including conditions and maintenance of certification requirements for HIT developers under the ONC Health IT Certification Program, the voluntary certification of HIT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. ONC and HHS stated that implementation of the proposed rule would advance interoperability and support the access, exchange, and use of electronic health information, as well as reduce burden and costs. Comments to the proposed rule are due by May 3, 2019.

Michigan Health Insurance Companies' Customers' Data at Risk After Vendor's Security Breach

On March 5, 2019 the *Detroit Free Press* reported that more than 120,000 Health Alliance Plan (HAP) clients' "personal and protected medical information may have been compromised in a security breach." Although the breach occurred on or around Sept. 23, 2018, when Wolverine Solutions Group (WSG) experienced a ransomware incident, WSG only notified HAP of the incident on Nov. 28th, but WSG was not certain of the extent of the breach until early February. WSG has sent out letters on behalf of HAP notifying customers of the breach only last week. Formal apologies have been issued by both HAP and WSG.

Since WSG performs mailing services for other clients, including health plans and hospital systems, they, too, were affected in the malware attack. The same breach may have also compromised about 150,000 Blue Cross Blue Shield of Michigan (BCBSM) customers, with about 100,000 of them residing in Michigan and others dispersed across many other states. BCBSM customers were notified in December of the breach and they offered their members "24 months of credit protection through AllClear ID." WSG has since migrated to a different computer system that has added protection and are training their workforce in safeguards to ensure there are no more incidents.

If you need assistance in managing a breach incident or making any required reporting, please contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

BRACH EICHLER LLC
bracheichler.com | Counsellors at Law

Health Care Practice Group | 101 Eisenhower Parkway, Roseland, NJ 07068 | 973.228.5700

Members

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Lani M. Dornfeld, HLU Editor | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Counsel

Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Lauren D. Goldberg | 973.364.5228 | lgoldberg@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Randall H. Lee | 973.364.5205 | rlee@bracheichler.com
Richard B. Robins | 973.403.3147 | rrobins@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com
Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com
Jocelyn Ezratty | 973.364.5211 | jezratty@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Erika Marshall | 973.364.5236 | emarshall@bracheichler.com

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HEALTH LAW ALERT APRIL 2019

MEDICAL AID IN DYING FOR THE TERMINALLY ILL ACT AWAITING SIGNATURE BY GOVERNOR MURPHY

On March 25, 2019, the Medical Aid in Dying for the Terminally Ill Act (Act) passed in both the New Jersey Assembly and New Jersey Senate and is now awaiting the signature of Governor Phil Murphy. The legislation permits a qualified terminally ill adult patient to obtain medication to self-administer in order to end the person's life. The bill contains numerous safeguards to ensure the process remains entirely voluntary and to protect the public welfare and vulnerable adults from abuse. Governor Murphy has until May 13, 2019 to sign the bill into law.

The Act is intended to recognize New Jersey's long-standing commitment to individual dignity, informed consent, and the fundamental right of competent adults to make health care decisions for themselves. These decisions include whether to have life-prolonging medical or surgical means or procedures provided, withheld, or withdrawn.

The Definition of Qualified Terminally Ill

The Act will permit a qualified terminally ill person who is an adult resident of New Jersey and has been determined by his/her attending and consulting physicians to be terminally ill to obtain life-terminating medication for self-administration. "Terminally ill" is defined to mean that the person is in the terminal stage of an irreversible fatal illness, disease, or condition with a prognosis, based upon reasonable medical certainty, of a life expectancy of six months or less. The diagnosis of terminal illness must be made by the patient's attending physician and confirmed by a consulting physician. In order to be deemed to "qualify," among other things, the individual must be a "capable" adult, meaning the person must have the capacity to make health care decisions and to communicate them to a health care provider, including communication through persons familiar with the patient's manner of communicating if those persons are available.

Informed and Carefully Considered Decision

The patient must make an "informed" decision, meaning that the traditional elements of the informed consent process must be satisfied. This includes that the patient's decision must be made after the patient is informed of and comprehends:

- The patient's medical diagnosis
- The patient's prognosis
- The potential risks associated with taking the medication to be prescribed
- The probable result of taking the medication to be prescribed
- The feasible alternatives to taking the medication, including additional treatment opportunities, palliative care, comfort care, hospital care, and pain control.

Once the patient has made a request for medication to terminate his/her life and before such medication is prescribed, the physician must ensure all required steps under the Act are taken, including:

- Ensuring the informed consent process has occurred
- Referring the patient to a consulting physician for medical confirmation of the diagnosis, prognosis, and patient "capability" to make the decision and confirming that the decision is being made voluntarily
- Referring the patient for counseling, if appropriate
- Recommending that the patient notify his/her next of kin of the decision
- Advising the patient of the importance of having another person present if and when the patient chooses to take the life-terminating medication, and not to take the medication in a public place
- Informing the patient of the opportunity to rescind his/her request

- Verifying that the patient is making an informed decision
- Fulfilling medical record documentation requirements and certain reporting requirements.

Additional Safeguards

The Act contains other safeguards against abuse, including that the individual must make two oral requests for life-terminating medication, with a 15-day separation between requests, followed by a written request on a form as required under the Act. The form must be signed by the individual and witnessed by at least two individuals, at least one of whom is not the patient's relative by blood, marriage, or adoption; who is entitled to any portion of the individual's estate; or in any way involved with the health care facility where the patient is receiving care or is a resident. Upon receipt of the written, signed, and witnessed request, the physician must wait at least 48 hours before writing the prescription for life-terminating medication.

Assistance

The Act contains a defined and safeguarded process to effectuate the right of a qualified terminally ill patient to obtain medication to end his/her life. The Act provides immunity to physicians and others who fully comply with the Act, and potential civil and criminal penalties for those who do not. Health care providers will need to institute detailed policies and procedures to ensure that every element of the Act is met.

*If you have any questions regarding the Act or would like assistance in preparing policies and procedures or otherwise implementing the requirements of the Act, feel free to contact **Lani M. Dornfeld, CHPC**, or another member of our health law practice group below.*

BRACH | EICHLER LLC

bracheichler.com | Counsellors at Law

Health Care Practice Group | 101 Eisenhower Parkway, Roseland, NJ 07068 | 973.228.5700

Members

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Lani M. Dornfeld, CHPC® | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Counsel

Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Lauren D. Goldberg | 973.364.5228 | lgoldberg@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Randall H. Lee | 973.364.5205 | rlee@bracheichler.com
Richard B. Robins | 973.403.3147 | rrobins@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com
Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com
Jocelyn Ezratty | 973.364.5211 | jezratty@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Erika Marshall | 973.364.5236 | emarshall@bracheichler.com

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