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Healthcare Law UPDATE

November 2021

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FEDERAL UPDATE

CMS Adopts COVID-19 Healthcare Staff Vaccination Interim Final Rule

On November 5, 2021, the Centers for Medicare & Medicaid Services (CMS) issued an Interim Final Rule requiring the vaccination of employees and staff of almost all Medicare and Medicaid-certified providers and suppliers that are regulated under the standards known as Conditions of Participation (CoPs). Key elements are set forth below.

Who Is Covered:

The rule covers the following Medicare and Medicaid-certified providers and suppliers: Ambulatory Surgery Centers, Community Mental Health Centers, Comprehensive Outpatient Rehabilitation Facilities, Critical Access Hospitals, End-Stage Renal Disease Facilities, Home Health Agencies, Home Infusion Therapy Suppliers, Hospices, Hospitals, Intermediate Care Facilities for Individuals with Intellectual Disabilities, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities (PRTFs) Programs for All-Inclusive Care for the Elderly Organizations (PACE), Rural Health Clinics/Federally Qualified Health Centers, and Long-Term Care Facilities. Of note: The rule does not apply directly to medical practices, but as noted below, does require physicians, other providers, and personnel who provide treatment at covered facilities to be vaccinated.

The vaccination requirement applies to eligible existing and new staff, regardless of clinical responsibility or patient contact. As such, a physician admitting and/or treating patients in-person within an applicable facility must be vaccinated. Individuals who provide services 100% remotely and who do not have any direct contact with patients and other staff, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements.

What Is Required:

The rule requires the applicable facilities to establish a process or policy to fulfill the staff vaccination requirements over two phases: For Phase 1, individuals at all covered facilities must have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine treatment by **December 6, 2021**. For Phase 2, individuals at all covered facilities must complete the primary vaccination series by **January 4, 2022**. The rule requires vaccination only and does not have a testing mandate. The rule also requires facilities to have policies in place that allow for exemptions for staff with recognized medical conditions for which the vaccines are contraindicated, or religious beliefs, observances, or practices.

How Will It Be Enforced:

CMS state survey agencies will conduct onsite compliance during the standard recertification survey cycle and also assess the vaccination status of staff on all other compliance surveys. Facility-specific accrediting organizations such as the Joint Commission will also be required to update their survey processes to assess compliance.

In addition, CMS has the ability, depending on the facility, to issue civil monetary penalties, denial of payment, and even termination, from the Medicare and Medicaid programs for lack of compliance. CMS has indicated in its published FAQs that its goal is to bring facilities into compliance, and that enforcement action would generally occur only after providing a facility with an opportunity to cure any noncompliance.

Implications with Other Laws:

If facilities are not subject to the rule, they may still be subject to the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors, OSHA's COVID-19 Healthcare Emergency Temporary Standard, or OSHA's COVID-19 Vaccination and Testing Emergency Temporary Standard (see article immediately below).

The rule became effective immediately upon publication on November 5, 2021. Any comments on the rule received before January 4, 2022 may be implemented in potential future rulemaking.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Caroline J. Patterson | 973.403.3141 | cpatterson@bracheichler.com

OSHA COVID-19 Vaccine ETS on Hold

On November 5, 2021, the U.S. Department of Labor Occupational Safety and Health Administration (OSHA) issued an emergency temporary standard (ETS) mandating that private employers with 100 or more employees implement a COVID-19 vaccination policy. Among other things, the ETS requires covered employers to:

- Develop, implement, and enforce a mandatory COVID-19 vaccination policy, with an exception for employers that instead establish, implement, and enforce a policy allowing employees to elect either to get vaccinated or undergo weekly COVID-19 testing and wear a face covering at the workplace.
- Determine the vaccination status of each employee, obtain acceptable proof of vaccination from vaccinated employees, maintain records of each employee's vaccination status, and maintain a roster of each employee's vaccination status.
- Provide up to four hours of paid time for employees to obtain the vaccines and reasonable paid sick leave for any vaccination side effects.
- Ensure unvaccinated employees are tested for COVID-19 at least weekly.

As of the publication of this *Healthcare Law Update*, more than two dozen states have joined in federal lawsuits seeking to reverse the ETS. On November 12, 2021, the U.S. Court of Appeals for the Fifth Circuit granted a motion to stay the ETS, ordering that OSHA "take no steps to implement or enforce" the ETS "until further court order." As a result, OSHA has "suspended activities related to the implementation and enforcement of the ETS pending future developments in the litigation."

For more information, contact:

Isabelle Bibet-Kalinyak | 973.403.3131 | ibibetkalinyak@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

CY2022 Medicare Physician Fee Schedule

The Centers for Medicare & Medicaid Services (CMS) announced the release of its 2,414 page Calendar Year 2022 Medicare Physician Fee Schedule Final Rule (MPFS) on November 2, 2021, along with a Fact Sheet. The MPFS Final Rule takes effect on January 1, 2022 and applies to Medicare Parts A and B. It aims to advance CMS' strategic commitment to driving innovation to support health equity and high-quality patient-centered care. "Promoting health equity, ensuring more people have access to comprehensive care, and providing innovative solutions to address our health system challenges are at the core of what we do at CMS," said CMS Administrator Chiquita Brooks-LaSure.

The rule provides numerous changes, including:

- Revising and clarifying certain Evaluation and Management (E/M) visits code sets (ongoing), including split or shared visits, critical care visits, and services furnished by teaching physicians involving residents.
- Promoting greater use of telehealth and other telecommunications technologies for providing behavioral healthcare services, including substance use disorders (SUDs), by allowing audio-only technology under very narrow circumstances.
- Encouraging the growth of the Medicare Diabetes Prevention Programs (MDPP).
- Boosting payment rates for influenza, pneumococcal, and shingles vaccine administration.
- Continuing to advance programs to improve the quality of care for Medicare beneficiaries by incentivizing clinicians to deliver improved outcomes.
- Giving physician assistants (PAs) the right to bill Medicare directly for their services.

The MPFS Final Rule appears broad and ambitious on the surface, but many of the progressive changes publicized by CMS remain limited to very narrow conditions as highlighted below in our Healthcare Law Alert on the MPFS Final Rule.

As always with the Medicare rules, providers need to analyze the new changes in context and in great detail to ensure that they satisfy all the requirements, and most importantly understand how to document said requirements in the medical records to prevent claim denials and costly repayments to CMS. Please refer to the full CY2022 MPFS Final Rule for all pertinent details.

For more information, contact:

Isabelle Bibet-Kalinyak | 973.403.3131 | ibibetkalinyak@bracheichler.com
John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com

OIG Issues Top Unimplemented Recommendations to Reduce Fraud, Waste, and Abuse

On November 4, 2021, the U.S. Department of Health & Human Services (HHS) released its annual publication, the OIG's Top Unimplemented Recommendations, which is a list of unimplemented HHS programs the Office of the Inspector General (OIG) believes would "most positively affect HHS programs in terms of cost savings, public health and safety, and program effectiveness and efficiency, if implemented." The 25 recommendations come from OIG audits and evaluations issued through December 31, 2020. Because of the evaluation timeframe, it should be noted that many recommendations predate the COVID-19 public health emergency. The OIG states that, as of September 21, 2021, it had 58 audits and evaluations underway related to COVID-19 response and recovery, which may result in recommendations that appear in future editions.

Aside from general recommendations HHS could implement at large, the recommendations span a wide range of different operating divisions, including the Centers for Medicare & Medicaid Services, the Administration for Children and Families, the Food and Drug Administration, the Indian Health Service, and the National Institutes of Health.

The recommendations vary in specificity from broad (e.g., "CMS should ensure that States' reporting of national Medicaid data is complete, accurate, and timely") to more precise (e.g., "CMS should pursue strategies to educate beneficiaries and providers about access to medication-assisted treatment drugs and naloxone – a drug that reverses opioid overdoses"), with some requiring legislative action. Alongside each recommendation are key findings from the OIG, the status or progress in implementing the recommendation, and relevant reports.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
James J. Ko | 973.403.3147 | jko@bracheichler.com

DOJ Announces New Actions to Combat Corporate Crime

On October 28, 2021, Deputy Attorney General Lisa O. Monaco announced that the U.S. Department of Justice (DOJ) is taking new action to strengthen the DOJ's response to corporate crime. One purpose of the announcement was to set forth the DOJ's new approach to corporate crime so that lawyers may provide well-informed advice to clients. The new actions set forth by the DOJ impact a board of directors' responsibilities regarding compliance measures and include an emphasis on individual accountability. The following are highlights of the new actions announced by the DOJ:

- To be eligible for credit for cooperating with an investigation, companies must provide the DOJ with all non-privileged information about all individuals involved in or responsible for the misconduct at issue, including identification of specific responsible individuals regardless of position, status, or seniority. Disclosures are no longer limited to those assessed to be "substantially involved" in misconduct.
- All prior misconduct will be evaluated when it comes to decisions about the proper resolution with a company. In weighing the appropriate resolution, prosecutors are directed to consider the full criminal, civil, and regulatory record of the company that is the subject or target of a criminal investigation.
- The DOJ is free to require the imposition of independent monitors whenever appropriate to satisfy prosecutors that a company is living up to its compliance and disclosure obligations. In opposition to previous DOJ guidance, monitoring will no longer be viewed as an exception and not the rule.
- Resources available to the DOJ shall be increased. For example, a new squad of FBI agents will be embedded in the DOJ's Criminal Fraud Section.

With the DOJ's new actions in place, boards must take steps to ensure legal compliance with all applicable laws and regulations, with an understanding that each board member bears personal responsibility for his or her conduct.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

What's in a Name? OIG Updates Its Health Care Fraud Self-Disclosure Protocol

On November 8, 2021, the Office of Inspector General (OIG) for the U.S. Department of Health & Human Services (HHS) renamed and updated its process for a party to voluntarily identify, disclose, and resolve instances of potential fraud involving federal healthcare programs. The OIG's prior Self-Disclosure Protocol is now known as the *Health Care Fraud Self-Disclosure Protocol* (the "Protocol"). More than just a name change, the OIG updated several parts of the Protocol, including:

- Requiring the disclosing party to include whether it is subject to a corporate integrity agreement (CIA). If so, the disclosing party must also send a copy of the voluntary disclosure to its CIA monitor.
- Requiring voluntary disclosures relating to an HHS grant or contract to be submitted to the OIG's separate grant self-disclosure program or contractor self-disclosure program.
- Requiring voluntary disclosures to be made online at the OIG's website. The online form allows for a party to submit attachments after submitting the form.
- Requiring voluntary disclosures to include the damages amount for each affected federal healthcare program and the sum of all damages for all affected federal healthcare programs.
- Increasing the minimum amount required to settle matters to $20,000 for false claims and $100,000 for anti-kickback-related conduct, which is consistent with recent legislative changes.

The OIG did not update other parts of the Protocol, including the methodology for calculating damages.

From 1998 to 2020, over 2,200 parties have made voluntary disclosures resulting in the OIG recovering over $870 million.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

CMS Issues 2022 Medicare Home Health Final Rule

The Centers for Medicare & Medicaid Services (CMS) recently released a Final Rule affecting home health, hospice, inpatient rehabilitation facilities, and long-term care facilities for calendar year 2022. The final rule becomes effective on January 1, 2022. It updates the home health services payment rates, various indexes, benchmarks and payment

categories for calendar year 2022 under the Home Health Prospective Payment System. The final rule also expands the Home Health Value-Based Purchasing Model to all Medicare-certified home health agencies across the United States, with full implementation effective beginning with calendar year 2023. The final rule also updates certain quality measures, compliance dates and reporting requirements under the Home Health Quality Reporting Program.

In addition, CMS will make permanent certain waivers related to home health aide supervision and home health visits by occupational therapists that were provided as a result of the COVID pandemic. The final rule updates the home infusion therapy services payment rates for calendar year 2022, including adjustments to the home infusion therapy services payment adjustment factors such as the geographic adjustment factors. The final rule addresses policies related to the effective date of enrollment of certain provider and supplier types and the deactivation of providers' or suppliers' billing privileges. The final rule also codifies certain revisions to the hospice survey process.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com

Invisalign Investors Are One Step Closer to $16 Million Settlement

Earlier this month, a California federal judge preliminarily approved a $16 million settlement with Align Technology, Inc. (Align), the manufacturer of Invisalign, a plastic form of dental braces known as aligners. In 2018 investors sued Align, claiming that the manufacturer deceived investors about the risks of competition because the patents for core product lines were expiring. Over the last three years, the Court has dismissed most of the investors' claims but this summer, after years of litigation and two mediations, the parties agreed to settle their dispute for $16 million.

In July, the investors presented their proposed settlement to the Court for approval as a class. If certified, the class will consist of anyone who purchased or acquired Align's common stock between May 23, 2018 and October 24, 2018. In support of the settlement, the investors acknowledged that absent settlement, the lead investor "would have faced substantial obstacles in proving its case." The final approval hearing for certification is scheduled for April 28, 2022.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com

ATTORNEY SPOTLIGHT

Get to know the faces and stories of the people behind the articles in each issue. This month, we invite you to meet Member Isabelle Bibet-Kalinyak and Counsel Jonathan J. Walzman.

Isabelle Bibet-Kalinyak

Isabelle Bibet-Kalinyak concentrates her national healthcare practice representing clients in complex business transactions including private equity transactions, mergers, and strategic partnerships, HIPAA privacy and security compliance matters, ownership and compensation arrangements, employment and partnership negotiations, medical staff matters, and fraud and abuse issues including compliance with the Stark Law and the Anti-Kickback Statute.

Outside of the office, Isabelle enjoys the arts, traveling to exotic destinations and her home country, France, scuba diving, running, and walking her two "babies," Coco and Louie. She has developed an eclectic palate, a diverse musical taste, and a love of adventure through her international voyages.

Jonathan Walzman

Jonathan Walzman concentrates his practice on corporate and healthcare transactions, with a focus on managing all aspects of corporate transactions involving medical practices, hospitals, licensed healthcare facilities and healthcare professionals, including mergers, acquisitions and divestitures, affiliation transactions, and financing transactions. Jonathan also advises healthcare practitioners, hospitals, and licensed facilities in regulatory compliance and licensure matters.

Jonathan enjoys spending time with his wife and three children, watching and playing sports with his kids, and traveling. He also is an active and involved member of his community, planning and coordinating community wide events for families and friends.

STATE UPDATE

Bill Introduced to Require Healthcare Facilities to Maintain Collective Bargaining Agreements Following a Sale

On November 8, 2021, Bill S4048 was introduced in the New Jersey Senate to require contracts for the sale of certain healthcare entities to preserve employee wages and benefits and to honor collective bargaining agreements. An identical bill was introduced in the New Jersey Assembly on November 15, 2021. The Bill defines "healthcare entity" as a licensed healthcare facility, a staffing registry, or a home care services agency. Specifically, the Bill provides that any contract or agreement for the sale or transfer of ownership or control of a healthcare entity would be required to provide the following: (1) if employees of the healthcare entity are covered by an unexpired collective bargaining agreement, the provisions of the collective bargaining agreement must remain in effect until the existing expiration date of the agreement or a date six months after the full effectuation of the sale or transfer, whichever is later; and (2) the wages and benefits, including healthcare, paid time off, retirement, and education benefits, of non-managerial employees of the healthcare entity who are not covered by an unexpired collective bargaining agreement will not be reduced or diminished during the period ending six months after the full effectuation of the sale or transfer.

Bill Introduced to Extend Temporary Emergency Licensure for Certain Healthcare Professionals

On November 12, 2021, Bill S4139 was introduced in the New Jersey Senate to extend the temporary authorization to practice for certain healthcare professionals that was authorized by the Division of Consumer Affairs in response to the COVID-19 pandemic. The Division had issued waivers authorizing certain healthcare professionals licensed in other states and certain healthcare professionals who recently graduated from an accredited program, but who had not yet met the requirements for full licensure, to practice in New Jersey to assist with the State's response to the COVID-19 pandemic. These temporary emergency licenses are currently set to expire on January 11, 2022. This Bill would provide that healthcare professionals authorized to practice under a temporary emergency reciprocal license, as well as nurses, physician assistants, respiratory care therapists, pharmacists, and alcohol and drug counselors authorized to practice under a temporary emergency graduate license would be permitted to continue practicing for an additional period of 60 days following the end of the federal public health emergency declared in response to the COVID-19 pandemic, i.e. until March 12, 2022.

Bill Introduced to Authorize Medical Cannabis Patients Under 18 to Have Up to Four Designated Caregivers

On November 12, 2021, Bill S4126 was introduced in the New Jersey Senate to authorize medical cannabis patients under 18 years of age to have up to four designated caregivers. Designated caregivers are individuals who are authorized to assist medical cannabis patients with acquiring and administering medical cannabis. Current law expressly allows all medical cannabis patients to have up to two designated caregivers, although patients may petition for approval to have additional designated caregivers, which petitions are to be granted if additional caregivers are consistent with the patient's treatment needs and the requirements of the State's medical cannabis laws.

Bill Introduced to Provide for Licensure of Pharmacy Benefits Managers

On November 12, 2021, Bill S4132 was introduced in the New Jersey Senate to provide for the licensure of pharmacy benefits managers. The proposed "New Jersey Pharmacy Benefits Manager Licensure and Regulation Act" had previously been introduced in the New Jersey Assembly. Under the Bill, the Commissioner of Banking and Insurance would create an application for a license to operate in New Jersey as a pharmacy benefits manager and would charge application fees and renewal fees. The Commissioner would also establish financial standards and reporting requirements for pharmacy benefits managers.

Board of Psychological Examiners Revises Records Retention Requirements

Effective November 1, 2021, the New Jersey State Board of Psychological Examiners regulations were revised to provide that licensed psychologists must retain records for minors for seven years from the date of the last entry or until the client turns 25 years of age, whichever is longer. Before the revision, licensed psychologists were only required to retain records for minors for seven years from the date of the last entry, which is the same as the requirement for adult records.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

Brach Eichler In The News

On November 16, Brach Eichler released the results to its 9th Annual New Jersey Healthcare Monitor Survey: 2022 Post-Pandemic Outlook for New Jersey's Healthcare Sector. Through this survey, the firm sought to ascertain how the healthcare community in New Jersey was affected by the COVID-19 pandemic and the tumultuous year that followed.

On November 13 and 14, Healthcare Law Member **Isabelle Bibet-Kalinyak** gave two presentations to the American Academy of Ophthalmology's 2021 Conference, "Private Equity Investors 2021: Game on!" and "Show Me The Money! Simulation of Vision Care M&A Transaction."

Brach Eichler has been named a 2022 Best Law Firm in New Jersey by Best Lawyers and *U.S. News & World Report*! The Firm was ranked in Metropolitan Tier 1 for Healthcare Law.

Managing Member and Healthcare Law Chair **John D. Fanburg** was named to *ROI-NJ's* Influencers: Health Care 2021 list.

On November 9, Healthcare Law Member **Isabelle Bibet-Kalinyak** was highlighted in *Law360* for bringing her depth and experience in healthcare to Brach Eichler.

HIPAA CORNER

OCR Releases Newsletter Addressing Legacy Systems and Protection of E-PHI Under HIPAA – On October 29, 2021, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR), released a newsletter regarding requirements under the HIPAA Security Rule for covered entities and their business associates concerning "Legacy Systems." Legacy Systems is a term for an information system with one or more components that have been supplanted by newer technology and for which the manufacturer is no longer offering support. The lack of vendor support for legacy systems makes them vulnerable to cyberattacks. The HIPAA Security Rule requires covered entities and their business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI, including ePHI used by Legacy Systems, and implement security measures to reduce those risks and vulnerabilities to a reasonable and appropriate level. Strategies proposed by OCR to mitigate a Legacy System's security risk, include, but are not limited to, the following:

- Contract with the vendor or a third party for extended system support or migrate the system to a supported cloud-based solution.
- Remove or segregate the Legacy System from the internet or the organization's network.
- Restrict access to the Legacy System to a reduced number of users.
- Strengthen authentication requirements and access controls.
- Implement supported anti-malware solutions.

Further, covered entities and business associates are required to review and modify their security measures to ensure continued protection of their ePHI. Ultimately, organizations must determine whether the burdens and costs of maintaining a Legacy System outweigh its benefits and plan for the Legacy System's eventual removal or replacement.

For more information or assistance with your privacy and security program or managing a breach incident, contact:

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

BRACH | EICHLER LLC
Counsellors at Law

Healthcare Law Practice | 101 Eisenhower Parkway, Roseland, NJ 07068

Members

Isabelle Bibet-Kalinyak | 973.403.3131 | ibibetkalinyak@bracheichler.com
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

Colleen Buontempo | 973.364.5210 | cbuontempo@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Caroline J. Patterson | 973.403.3141 | cpatterson@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Associates

Lindsay P. Cambron | 973.364.5232 | lcambron@bracheichler.com
Paul J. DeMartino, Jr. | 973.364.5228 | pdemartino@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com
Emily J. Harris | 973.364.5205 | eharris@bracheichler.com
James J. Ko | 973.403.3147 | jko@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Erika R. Marshall | 973.364.5236 | emarshall@bracheichler.com

Roseland, NJ | New York, NY | West Palm Beach, FL | www.bracheichler.com | 973.228.5700