HEALTHCARE LAW UPDATE

IN THIS ISSUE:

STATE UPDATE

Shore Memorial Health System Settles False Claims Act Allegations Over Improper Receipt of PPP Loan

In August 2024, Shore Memorial Health System Inc., based in Atlantic County, New Jersey, and an affiliated medical practice agreed to a settlement with the United States to resolve allegations that it violated the False Claims Act by obtaining a Paycheck Protection Program (PPP) loan that it was not entitled to receive. The PPP loan program was established in March 2020 under the Coronavirus Aid, Relief, and Economic Security (CARES) Act to provide financial support to small businesses impacted by the COVID-19 pandemic through forgivable loans to cover payroll and essential expenses.

Shore Memorial Physicians' Group (SPG), an affiliate of the Health System, applied for and was granted a $2.78 million PPP loan. SPG later sought and obtained forgiveness for the entire loan amount. However, SPG was ineligible for the loan due to its affiliation with the Health System, which disqualified it from being classified as a small business under the PPP loan program. In accordance with the terms of the settlement, the Health System and SPG agreed to pay the United States $3.15 million. The settlement also resolves a lawsuit brought under the whistleblower provisions of the False Claims Act, with the whistleblower receiving $315,000.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com
Vanessa Coleman | 973.364.5208 | vcoleman@bracheichler.com

Nursing Home Association Sues New Jersey DOH to Void Minimum Staffing Requirements

The Heath Care Association of New Jersey (HCA), a trade group representing New Jersey nursing homes, together with several nursing homes recently filed a lawsuit against the New Jersey Department of Health seeking to void a 2020 New Jersey law that sets minimum staffing requirements for New Jersey nursing homes, arguing that staffing shortages make the law an "unworkable and impossible mandate." The law requires New Jersey licensed nursing homes to maintain certain staff to resident ratios for both day and night shifts. The law was adopted in response to the COVID-19 pandemic, during which New Jersey nursing homes saw high death tolls and infection rates.

The HCA's lawsuit seeks to void and delay enforcement of the staffing ratio law on the grounds that it is unconstitutional and impossible for nursing homes to comply with. The HCA claims that the fines being assessed by the DOH for failure to comply, which by statute amount to $1,000.00 per day of noncompliance, are excessive and violate the New Jersey Constitution. The HCA also argues that the law was adopted notwithstanding a State study that found that New Jersey's direct care workforce is shrinking and cannot meet the needs of the State's growing elderly population. According to the HCA, the number of people willing to work in nursing homes has declined by almost fifteen percent since the onset of the COVID-19 pandemic, resulting in a lack of enough available Certified Nursing Aides to make compliance with the staffing law possible. In addition to the lack of available practitioners, New Jersey nursing homes are also faced with a rapid increase in the number of individuals over the age of 65 coupled with increased expenses, with no corresponding increase in Medicaid reimbursement.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Richard Robins | 973.447.9663 | rrobins@bracheichler.com
Paul DeMartino, Jr. | 973.364.5228 | pdemartino@bracheichler.com

Governor Murphy Forgives $100 Million in Medical Debt

On August 20, 2024, Governor Phil Murphy announced that medical debt for almost 50,000 New Jersey residents totaling $100 million dollars will be eliminated. The Murphy administration was able to eliminate the debt by leveraging federal funds from the American Rescue Plan and partnering with Undue Medical Debt, a non-profit that works with hospital systems to purchase and eliminate large bundled portfolios of medical debt. Those that qualify for such medical debt relief have annual income which is below four times the federal poverty level or have medical debts that equal 5% or more of their annual income. Medical debt relief cannot be requested as it is dependent upon providers, such as hospitals, who choose to engage in the program. New Jersey residents that qualify for such medical debt relief began receiving letters from Undue on August 19, 2024.

The announcement follows the signing of the Louisa Carman Medical Debt Relief Act by Governor Murphy in July 2024, which protects individuals from predatory medical debt collectors and prohibits the reporting of medical debt to credit reporting agencies.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

FEDERAL UPDATE

Final Rules Adopted to Advance Mental Health Parity

On September 9, 2024, the Departments of Health and Human Services, Labor and the Treasury issued new final rules for the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA). These new final rules amend certain provisions of the existing MHPAEA and add new regulations to MHPAEA. The purpose of these final rules is to ensure that beneficiaries of group health plans and individual health insurance plans receive coverage for covered mental health conditions or substance use disorders and do not face greater burdens in accessing such benefits than they would when seeking coverage for the treatment of a medical condition or surgical procedure. Among other things, the final rules require that health plans and insurers not use non-quantitative treatment limitations (NQTLs) that are more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits in the same classification. Examples of such NQTLs include prior authorization requirements, standards related to network composition; and methodologies to determine out of network reimbursement rates. The final rules also prohibit health insurance plans and insurers from using discriminatory information, evidence, sources, or standards that systemically disfavor or are specifically designed to disfavor access to mental health or substance abuse disorders benefits as compared to medical/surgical benefits when designing NQTLs. A majority of the provisions of the final rules go into effect January 1, 2025, however certain requirements which may take more time to implement, such as putting into place data evaluation requirements, will go into effect January 1, 2026.

For more information, contact:

Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com
Edward Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Erika R. Marshall | 973.364.5236 | emarshall@bracheichler.com

Not-For-Profit's Patient Assistance Program Receives Favorable Advisory Opinion

On August 23, 2024, the Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion No. 24-07, allowing a not-for-profit organization to establish a patient assistance program (PAP) to subsidize cost-sharing obligations for low-income diabetic Medicare enrollees.

The requestor sought to pay the cost-sharing obligations for diabetes drugs for Medicare Part D enrollees who reside in the community it serves. To qualify, Part D enrollees must have no secondary insurance coverage, a household income below 400% of the Federal Poverty Level (FPL) and submit an enrollment application to the requestor. The requestor would allocate funding on a first-come first-serve basis. Under the proposed arrangement, participants can use any pharmacy. However, if participants use a "Preferred Pharmacy," the requestor would pay the cost-sharing up front. Otherwise, participants would pay their cost-share to the pharmacy and receive reimbursement from the requestor.

Although the cost-sharing subsidies and the use of a "Preferred Pharmacy" would each generate remuneration, the OIG issued a favorable opinion, stating that the risk of fraud and abuse is "sufficiently low" for the reasons set forth below.

Cost-Sharing Subsidies:

1. The subsidies would not function as a "conduit for payments by a pharmaceutical manufacturer" because the requestor is independent of pharmaceutical influence and does not solicit or receive donations from or on behalf of a pharmaceutical entity.
2. There is a low likelihood that the subsidy would steer Medicare beneficiaries to a particular drug because the subsidy would apply to all FDA-approved diabetes medications that are covered by Part D.
3. The subsidy would not induce participants to purchase drugs because eligibility is based on strict need-based criteria and is subject to annual re-enrollment and funding limitations.

Enabling Participants to Avoid Out-of-Pocket Expenses by Using a Preferred Pharmacy:

1. The risk of steering patients to a Preferred Pharmacy is low because participants use other factors when selecting a pharmacy, such as location and drug availability, and the dollar value of the subsidy does not differ based on the pharmacy used.
2. The use of a Preferred Pharmacy is unlikely to interfere with clinical decision-making or otherwise induce a participant to purchase a prescription drug.
3. The arrangement is unlikely to increase costs to Federal health care programs because Federal health care programs will pay the same amount, regardless of the pharmacy used.

For more information, contact:

Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com
Rebecca Falk | 973.364.8393 | rfalk@bracheichler.com

Court Rules that Earnout Violates New York Fee-Splitting Rules

In a recently published opinion, a New York appellate court found that an earnout based on future practice earnings that was negotiated as part of a practice sale violated New York's fee-splitting prohibition. In 2015, the plaintiff, a dental practice, entered into an asset purchase agreement to sell certain assets to the defendant, a licensed dentist who retained his own separate practice. The purchase agreement specified that part of the purchase price would be paid by the purchaser to the seller as a percentage of the monthly revenue generated by the practice assets that the seller sold to the purchaser.

In March 2020, the seller filed a lawsuit against the purchaser alleging breach of contract and unjust enrichment as a result of the purchaser's failure to pay the earnout portion of the purchase price to the seller. The purchaser filed a motion to dismiss, arguing that the arrangement violated the provisions of New York's Education Law that prohibits fee-splitting. The trial court denied the motion to dismiss. On appeal, the appellate court overturned the trial court's decision to deny the purchaser's motion to dismiss, finding that the earnout constituted a voluntary prospective arrangement for the splitting of fees in violation of New York law, and "a party to an illegal contract cannot ask a court of law to help him or her carry out his or her illegal object."

For more information, contact:

Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Andrew Kuder | 973.403.3141 | akuder@bracheichler.com

CMS Reports more than 12,000 No Surprises Act Complaints So Far this Year

The Centers for Medicare and Medicaid Services (CMS) recently released a report regarding complaints and enforcement efforts concerning No Surprises Act. According to the report, CMS received more than 12,000 complaints of No Surprises Act violations through June 30, 2024. Of those complaints, nearly 2,000 were against payors and over 10,000 were against providers, including individual providers, health care facilities and air ambulance providers. According to the report, CMS has directed payors and providers to take remedial corrective actions to address instances of non-compliance with the No Surprises Act, resulting

in over $4 Million in monetary relief paid to consumers or providers. The No Surprises Act was signed into law in 2020 and took effect at the beginning of 2022. The law is intended to prevent "surprise bills" by ensuring that providers inform patients in advance of the cost of receiving care and whether or not the provider is in-network or out-of-network with the patient's insurance plan.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Andrew Kuder | 973.403.3141 | akuder@bracheichler.com

LEGISLATIVE AND REGULATORY UPDATE

Bill Introduced to Establish Board of Paramedicine

Senate Bill No. 3563, introduced in the New Jersey State Senate on September 12, 2024, would establish the New Jersey Board of Paramedicine. The Board would oversee mobile intensive care paramedics, emergency medical technicians, mobile intensive care nurses, flight paramedics, and flight nurses. Paramedicine would be defined as the practice of basic life support and advanced life support. "Basic life support" would mean pre-hospital care, including the use of procedures, medications, and equipment established by the National EMS Scope of Practice Model from the National Highway Traffic Safety Administration and such other techniques or therapies authorized by the Board. "Advanced life support" would mean an advanced level of emergency medical care, including specialty care transport and air medical ambulances, including the use of procedures, medications, and equipment established by the National EMS Scope of Practice Model from the National Highway Traffic Safety Administration and such other techniques or therapies authorized by the Board. The Board would be authorized to develop the standards for an individual seeking licensure; establish standards for schools seeking to provide training; and develop a registry for individuals who have completed training and necessary evaluation programs. If the Board is created, all current laws governing mobile intensive care paramedics and emergency medical technicians would be repealed and the Board would have oversight over these professions.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Edward Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com
Erika R. Marshall | 973.364.5236 | emarshall@bracheichler.com

HIPAA CORNER

OCR Cybersecurity Newsletter Highlights Importance of Facility Access Controls

In its August 2024 Cybersecurity Newsletter, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR), the HIPAA enforcement agency, provided important information regarding facility access controls. According to the OCR,

> From 2020 through 2023, the Office for Civil Rights (OCR) received over 50 large breach reports (i.e., breaches of unsecured protected health information (PHI) involving 500 or more individuals) affecting over 1,000,000 individuals attributable to stolen equipment and devices containing ePHI. Such equipment and devices were frequently described as being stolen during a burglary and included workstations, servers, laptops, external hard drives, backup devices, flash drives, smart phones, and medical devices. Regulated entities should ensure that they have proper physical safeguards, including Facility Access Controls, in place to deter and prevent unauthorized access.

The OCR provided an example of a monetary settlement of an OCR investigation in the amount of $3.5M, relating to, among other things, the theft of equipment from a covered entity's facilities.

Among the requirements of the HIPAA Security Rule is the requirement for covered entities and their business associates to implement ongoing facility access controls – policies and procedures to limit physical access to the organization's information systems and the facility or

facilities in which such information systems are housed, while at the same time ensuring that those whose job functions require access to such systems are granted secure access. This is accomplished by implementing four addressable implementation specifications: (1) contingency operations, (2) facility security plan, (3) access control and validation procedures, and (4) maintenance records.

The OCR newsletter contains details about each of these specifications and provides links to additional resources.

If you need assistance with your HIPAA compliance program, an OCR investigation, or a data breach incident, please contact:

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

BRACH EICHLER IN THE NEWS

Save the Date!! The 13th Annual New Jersey Healthcare Market Review, April 3-4, 2025 at the Borgata Hotel Casino & Spa, Atlantic City, NJ! Connect with over 200 attendees, comprised of hospital and ASC executives and stakeholders, physicians, practice owners/managers, and healthcare administrators. During this two-day event, industry experts will discuss timely topics and trends in the healthcare and legal space ranging from legislative issues to operating and business strategies for greater profitability. To learn more and register, please visit https://www.njhmr.com. For questions or additional information, please reach out to Jennifer Buneta at jbuneta@bracheichler.com.

Mark your calendars! On October 2, Brach Eichler attorney **Ashley L. Matias** will be presenting a Lawline webcast entitled "Navigating Pregnancy Discrimination: Legal Obligations and Best Practices."

On September 27, Chair of Brach Eichler's Healthcare Law Practice **John D. Fanburg, Esq**. and Vice Chair **Isabelle Bibet-Kalinyak, Esq.** presented a Legal and Regulatory Update at the 2024 New Jersey Academy of Ophthalmology Annual Meeting.

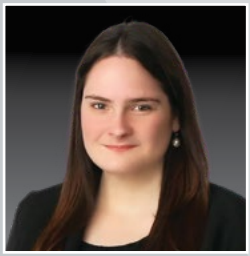
On September 24, Chair of Brach Eichler's Health Law Practice **John D. Fanburg, Esq** and Member **Carol Grelecki, Esq.** provided a regulatory update on key changes in New Jersey healthcare law at the Radiological Society of New Jersey (RSNJ) Annual Meeting.

On September 10, Vice Chair of Brach Eichler's Healthcare Law Practice, I**sabelle Bibet-Kalinyak, Esq.** and **Joseph Gorrell, Esq.** announced that Brach Eichler acted as the exclusive legal advisor to New Jersey Cancer Care, PA ("NJCC") in its partnership with Regional Cancer Care Associates ("RCCA").

On September 5, Chair of Brach Eichler's Healthcare Law Practice **John D. Fanburg, Esq.** and Vice Chair **Isabelle Bibet-Kalinyak, Esq.** presented the legislative and legal update at New Jersey Association of Ambulatory Surgery Centers on the recently enacted Medical Debt Relief Act.

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 Counsel Cynthia J. Liba and Counsel Paul DeMartino, Jr.



CYNTHIA J. LIBA

What is an interesting trend in Healthcare Law?

An emerging trend in many sectors including healthcare, is the prevalence of artificial intelligence. The legal landscape will continue to evolve in order to address concerns connected to the use of artificial intelligence. As an example, the use of artificial intelligence technology must be HIPAA compliant to ensure that patient privacy is protected.

What achievement are you most proud of?

I am proud of the trusted relationships I have built with clients that allows us to work together collaboratively and achieve optimal results.

PAUL DEMARTINO, JR.

What is an interesting trend in Healthcare Law?

One interesting trend is the intersection between private equity acquisitions of healthcare practices and the FTC's attempt to ban non-compete agreements. While private equity acq uisitions have come under scrutiny, often times these transactions will contain non-compete agreements for the physicians so the new entity can protect their investment. Ev en under the FTC's proposed ban of non-compete agreements (which was blocked by a federal judge in Texas) covenants relating to sale of a business would be enforceable. However, the corporate practice of medicine statutes coupled with the shortage of physicians in various specialties gives rise to an interesting argument as to whether the non-compete agreement in the private equity context is enforceable in a court of law.

What achievement are you most proud of?

Obtaining a $7.6M judgment after a two-week arbitration hearing on behalf of a group of physicians in a partnership dispute with their former practice.

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HEALTHCARE LAW PRACTICE | 101 EISENHOWER PARKWAY, ROSELAND, NJ 07068

MEMBERS

Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com
Shannon Carroll | 973.403.3126 | scarroll@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Lani M. Dornfeld | 973.403.3136 | ldornfeld@bracheichler.com
John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Joseph A. Ferino | 973.364.8351 | jferino@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Edward Hilzenrath, HLU Editor | 973.403.3114 | ehilzenrath@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Richard Robins | 973.447.9663 | robins@bracheichler.com
Jonathan J. Walzman | 973.403.3120 | jwalzman@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

COUNSEL

Paul J. DeMartino, Jr. | 973.364.5228 | pdemartino@bracheichler.com
Edward Ellersick | 973.364.52052 | eellersick@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Erika R. Marshall | 973.364.5236 | emarshall@bracheichler.com

ASSOCIATES

Vanessa Coleman | 973.364.5208 | vcoleman@bracheichler.com
Rebecca T. Falk | 973.364.8393 | rfalk@bracheichler.com
Andrew Kuder | 973.403.3141 | akuder@bracheichler.com

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

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