FEDERAL HEALTHCARE LAW **UPDATE**

FTC Adopts Final Rule Banning Workplace Non-Compete

On April 23, 2024, the Federal Trade Commission (FTC) adopted a broad regulation that will void employer contracts, workplace policies, and compensation arrangements that prohibit, penalize, or in practice prevent a worker from working elsewhere (save for a few limited exceptions) when, and if, the ban goes into effect as scheduled in mid-August 2024.

The FTC rule bans all non-competes with two general exceptions. First, the rule does not ban any non-competes in existence as of mid-August 2024 with a worker who is a senior executive in a policy-making position who received total compensation of at least $151,164 in the preceding year. Note, not all salaried executives will fall within this exception. To be exempt the senior executive will need to be the organization's president, CEO "or the equivalent," another officer (such as a vice president, secretary, treasurer or principal financial officer, comptroller or principal accounting officer) with policy-making authority, or a person with policy-making authority similar to an officer with policy-making authority.

"Policy-making authority" for purposes of this exception "means final authority to make policy decisions that control significant aspects of a business entity or common enterprise." Applying this exception to closely-held organizations, such as a medical practice, will require careful analysis of the actual business functions of each manager and equity holder. This exception does not apply to non-competes entered into after the rule goes into effect.

Second, the ban does not apply when "entered into by a person pursuant to a bona fide sale of a business entity, of the person's ownership interest in a business entity, or of all or substantially all of a business entity's operating assets." This exception applies even if the person sells only a minority stake in the business and regardless of the financial size of the transaction.

All private sector, for-profit businesses are subject to the FTC rule. However, not all non-profit organizations are subject to the FTC rule because the FTC has jurisdiction only over statutory corporations. In issuing its rule, the FTC cautioned that "that not all entities claiming tax-exempt status as nonprofits fall outside the [FTC's] jurisdiction. . . . Merely claiming tax-exempt status in tax filings is not dispositive." The FTC cited, for example, its prior exercise of jurisdiction over an independent physician association claiming tax-exempt status as a nonprofit. Nonprofit organizations will, therefore, have to conduct a detailed analysis of the scope of the FTC's jurisdiction.

The FTC rule applies to more than just contracts that prohibit working elsewhere. The rule also applies to any policy or arrangement that "penalizes" a worker from working elsewhere or that "functions to prevent a worker from" working elsewhere. Deferred compensation arrangements that condition the payment of compensation on the person not working elsewhere will be considered non-competes. Similarly, certain employee loans and advances may be considered non-competes, as may be overly broad non-solicitation and confidentiality agreements. Any person who provides services to a regulated organization is covered, even if the person is treated as an independent contractor or is a sole proprietor. Importantly, the FTC rule applies only to limitations on a worker's ability to work elsewhere after the current engagement. It does not apply to limitations on concurrent employment, such as a policy that prevents or limits moonlighting.

Court challenges have already been filed against the implementation of the rule and an injunction is expected before the rules goes into effect in mid-August. The Ambulatory Surgery Center Association (ASCA) had submitted public comments

opposing the proposed rule in April 2023, but did not take a position on the appropriateness of noncompete clauses generally. ASCA commented that "[u]nder this proposal, surgery centers and other tax-paying healthcare providers would be subject to restrictions that tax-exempt systems would not. Hospitals are more likely to employ physicians currently, and this rule would allow nonprofit providers to more aggressively engage in noncompetitive behavior that would impede a physician's ability to eventually move to an ASC or other healthcare provider."

ASCA notes that the final rule is already facing legal challenges, notably from the U.S. Chamber of Commerce, which filed a lawsuit on April 24, 2024, just one day after the final rule was issued, seeking an injunction against its implementation. With additional legal challenges expected, ASCA will continue to monitor developments closely.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com

U.S. Department of Health Clarifies Informed Consent Guidance for Sensitive Medical Examinations

On April 1, 2024, the United States Department of Health and Human Services (HHS) issued new guidance clarifying the obligation of hospitals to obtain a patient's written consent prior to performing certain sensitive exams, such as pelvic, breast or prostate exams, particularly with respect to patients who are under anesthesia during the exam. The new guidance was issued as a result of public scrutiny regarding the practice of allowing practitioners or supervised medical, advanced practice providers or other healthcare students to perform sensitive examinations that are not related to the condition for which the patient is seeking treatment, such as breast, pelvic, prostate, and rectal examinations, for training and education purposes, including on patients who are under anesthesia. In its new guidance, HHS emphasizes that a hospital's informed consent policy and process, and all informed consent forms, must ensure that patients are provided with sufficient information to allow them to make informed decisions regarding the full scale of care they are to receive. Hospitals that fail to adhere to the updated informed consent guidelines may be subject to investigations, fines and sanctions.

For more information, contact:

Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com
Edward J. Yun | 973.364.5229 | eyun@bracheichler.com

Proposed American Privacy Act

On April 7, 2024, the U.S. Senate Committee on Commerce, Science, & Transportation issued a press release about the proposed American Privacy Rights Act (Act). "This comprehensive draft legislation sets clear, national data privacy rights and protections for Americans, eliminates the existing patchwork of state comprehensive data privacy laws and establishes robust enforcement mechanisms to hold violators accountable, including a private right of action for individuals." In summary, the proposed law would (1) establish foundational uniform national data privacy rights for Americans, (2) give Americans the ability to enforce their data rights, (3) protect Americans' civil rights, (4) hold companies accountable and establishes strong data security obligations, and (5) focus on the business of data, not mainstream business. The proposed Act defines "covered data" as "information that identifies or is linked or reasonably linkable, alone or in combination with other information, to an individual or a device that identifies or is linked or reasonably linkable to one or more individuals" residing in the U.S. Sensitive covered data includes, among other data, government identifiers, and a "covered entity" is any entity that determines the purpose and means of collecting, processing, retaining, or transferring covered data and is subject to the Federal Trade Commission Act, including common carriers and certain nonprofits.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com

Litigation Against Private Equity Backed Anesthesia Provider Expands

Recently, hospitals in New York and Florida filed complaints against affiliates of North American Partners in Anesthesia (NAPA) alleging that the anesthesia provider's non-compete agreements were unenforceable. The claims made by the hospitals largely mirror the claims made in the summer of 2022 by RWJBarnabas Health against the NAPA affiliate in New Jersey.

Specifically, the hospitals allege that NAPA failed to properly staff their anesthesia departments and failed to share in the risk of excessive costs. Instead, NAPA simply demanded that the nonprofit hospitals continue to pay increased costs for diminishing services. In response, the hospitals attempted to negotiate a separation from the anesthesia provider. NAPA, in turn, demanded millions of dollars to waive underlying noncompete agreements. The hospitals took action and sued NAPA challenging the enforceability of NAPA's noncompete agreements.

On March 19, 2024, a New York District Court denied NAPA's application seeking temporary enforcement of the noncompete agreement during the pendency of the lawsuit. The Court found that NAPA failed to establish (1) that it would be irreparably harmed if the noncompete agreements were not enforced and (2) that NAPA had a likelihood of success on the merits. In its opinion, the Court noted that this is not a dispute between physicians; rather, this is a dispute between a hospital and an anesthesia management company. NAPA then made an application for the same relief on a permanent basis. The motion is set for argument before the Court on May 1, 2024.

These cases are significant, because they challenge the enforceability of noncompete agreements held by unlicensed management companies against licensed professionals.

For more information, contact:

Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com

Medicare To Cover Weight Loss Drug to Reduce Risk of Cardiovascular Disease

On March 21, 2024, the Centers for Medicare and Medicaid Services (CMS) announced that Wegovy, a prescription weight loss medication developed by Novo Nordisk, would now be eligible for coverage under Medicare Part-D for the specific use of reducing the risk of death attributable to cardiovascular disease in overweight or obese individuals. Medicare currently is not permitted by law to cover drugs used solely for chronic weight management, although Medicare may cover a drug that is used for weight loss if it also receives U.S. Food and Drug Administration (FDA) approval for another medically accepted use, like treating cardiovascular disease.

CMS' approval of coverage for Wegovy comes less than 2 weeks after the FDA announced that it would approve Wegovy for the preventative treatment of cardiovascular disease in those who are obese or overweight. The FDA's approval was based on an international, multi-year study of 17,000 overweight or obese patients, with results showing that those individuals taking Wegovy had a 20% lower risk of an adverse cardiac event, such as heart attack or stroke, than those taking a placebo.

Despite a current supply shortage, the demand for Wegovy has never been higher, even with the average current cost of the drug exceeding $1,000 per month. The continuous surge in demand can likely be attributed to America's ongoing obesity crisis. According to the latest statistics, it is estimated that nearly half of all adults in the U.S. have some form of cardiovascular disease, while 73.1% of all U.S. adults are considered overweight or obese. Even with the "limited scope" of coverage approval by CMS, most private insurers have indicated a reluctance to follow suit.

For more information, contact:

John D. Fanburg, Chair | 973.403.3107 | jfanburg@bracheichler.com
Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com

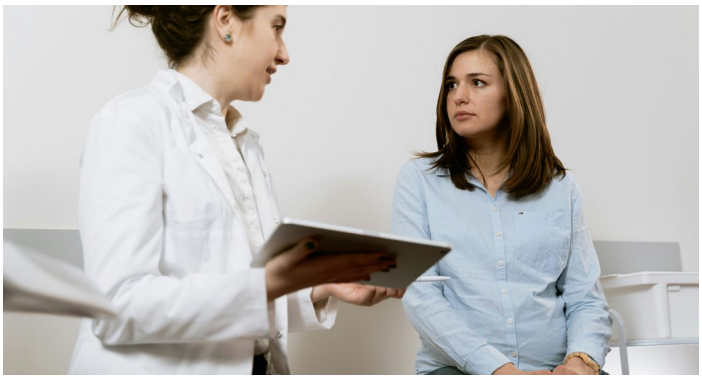
LEGISLATIVE AND REGULATORY UPDATE

Stark Law - 2024 *De Minimis* Compensation Limit

The Stark Law stipulates that when there is a financial relationship between an entity and a physician, the physician cannot refer patients to that entity for "designated health services" and the entity cannot charge for those services, unless they meet certain exceptions. The term "financial relationship" encompasses any form of compensation from the entity to the physician, including non-monetary benefits. Any form of remuneration provided to a physician (or his or her family members or office staff), whether directly or indirectly, carries the risk of implicating federal laws such as the Stark Law (42 U.S.C. § 1395nn) and the Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), as well as equivalent state statutes. Pursuant to the implementing regulations to the Stark Law (42 C.F.R. § 411.357), there are exceptions to the above for certain types of compensation to physicians, including non-monetary compensation such as meals, Medical Staff incidental benefits, and limited remuneration. Under these exceptions, the non-monetary compensation limits are adjusted each calendar year by the increase in the Consumer Price Index-Urban All Item (CPI-U) for the 12-month period ending the preceding September 30. The 2024 non-monetary compensation limit for meals is $507, the Medical Staff incidentals' limit is $47, and the remuneration limit is $5,913.

2024's Monetary Cap for Modest Meals (NJ)

The New Jersey Division of Consumer Affairs posted on April 1, 2024 its annual update regarding how much a prescriber may accept from a pharmaceutical manufacturer, when he/she is not speaking or providing services at a promotional activity. The "modest meals" cap for 2024 is $19.00 for breakfast or lunch and $40.00 for dinner.



HIPAA CORNER

HIPAA Privacy Rule to Support Reproductive Health Care Privacy – Final Rule

On April 22, 2024, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) announced a final rule, titled *HIPAA Privacy Rule to Support Reproductive Health Care Privacy* (Final Rule). The rule will become effective 60 days after formal publication in the Federal Register, with a final compliance deadline of 240 days after publication, except for certain requirements that must be complied with by February 16, 2026. Please find Brach Eichler's in-depth alert to this topic by clicking on this link.

OCR Creates FAQ Webpage In Response to Change Healthcare Cyberattack

On April 19, 2024, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) posted a new webpage containing frequently asked questions (FAQs) concerning HIPAA and the Change Healthcare cybersecurity incident. The FAQs, in part, address the fact that on March 13, 2024, the OCR published a "Dear Colleague Letter" advising that the OCR was aware of the Change Healthcare cybersecurity incident that occurred in late February 2024 "that is disrupting health care and billing information systems nationwide."

Some of the FAQs covered include:

- Why did OCR issue the March 13, 2024, "Dear Colleague Letter"?
- Why is OCR initiating an investigation and what does it cover?
- Has OCR received breach reports from Change Healthcare, UHG, or any affected health care providers?
- Are covered entities that are affected by the cyberattack involving Change Healthcare and UHG required to file breach notifications?

- What HIPAA breach notification duties do covered entities have with respect to the Change Healthcare cyberattack?
- What HIPAA breach notification duties do business associates have with respect to the Change Healthcare cyberattack?

Personal Information Was Breached in Change Healthcare Cyberattack

On April 22, 2024, UnitedHealth Group issued a press release announcing that:

Based on initial targeted data sampling to date, the company has found files containing protected health information (PHI) or personally identifiable information (PII), which could cover a substantial proportion of people in America. To date, the company has not seen evidence of exfiltration of materials such as doctors' charts or full medical histories among the data. Although UnitedHealth states that "Change Healthcare has made continued strong progress restoring services impacted by the event," the far-reaching consequences of the event are still unfolding. The company set up a dedicated support website to provide support for people concerned about their personal data due to the attack, as well as a call center hotline number, 1-866-262-5342.

Dozens of Class Action Lawsuits Against Change Healthcare

Dozens of class action lawsuits have been filed in different districts around the United States against Change Healthcare relating to the cyber attack announced by the company in late February 2024. On April 3, 2024, Change Healthcare filed a Motion seeking to consolidate the cases to its home town district, the United States District Court for the Middle District of Tennessee. While some of these class actions were filed by providers affected by the disruption to payments for medical services rendered, others were filed by individuals alleging the company did not have sufficient cybersecurity measures in place to prevent the data breach, allowing threat actors to potentially expose sensitive health and personal information. The filing of additional lawsuits is likely as the facts continue to evolve.

Cyber Incident Reporting for Critical Infrastructure Act (CIRCIA) Proposed Regulations

On April 4, 2024, the U.S. Department of Homeland Security published a proposed rule to implement the Cyber Incident Reporting for Critical Infrastructure Act of 2022 (CIRCIA). CIRCIA requires any critical infrastructure company (a covered entity under the statute) to report to the Cybersecurity and Infrastructure Security Agency (CISA) within certain prescribed timeframes any substantial cyber incident (a covered event), ransom payment made in response to a ransomware attack, and any substantial new or different information discovered related to a previously submitted report.

CISA estimates that the proposed rule will apply to approximately 316,000 covered entities, whom are in one of 16 enumerated Critical Infrastructure sectors and either (i) do not qualify as a small business as defined by the Small Business Administration, or (ii) meet a sector-based criterion. According to CISA under the Healthcare and Public Health (HPH) Sector-Specific Plan, the "HPH Sector is large, diverse, and open, spanning both the public and private sectors. It includes publicly accessible healthcare facilities, research centers, suppliers, manufacturers, and other physical assets and vast, complex public-private information technology systems required for care delivery and to support the rapid, secure transmission and storage of large amounts of HPH data."

CISA's summary of the rule proposal may be found here and Critical Infrastructure Sector information may be found here.

OCR Publishes Updated Guidance on the Use of Online Tracking Technologies

On March 18. 2024, the U.S. Department of Health & Human Services, Office for Civil Rights (OCR) published updated guidance regarding the use of online tracking technologies by HIPAA covered entities and business associates. In short, "[r]egulated entities are not permitted to use tracking technologies in a manner that would result in impermissible disclosures of PHI to tracking technology vendors or any other violations of the HIPAA Rules. For example, disclosures of PHI to tracking technology vendors for marketing purposes, without individuals' HIPAA-compliant authorizations, would constitute impermissible disclosures" under HIPAA.

With the proliferation of tracking technologies and tracking technology vendors, and the OCR's increasing attention to the use of such technologies and vendors in the health care sector, HIPAA covered entities and their business associates should take heed and examine how their websites and mobile apps are actually functioning and make appropriate changes to ensure HIPAA compliance.

Proposed American Privacy Rights Act

On April 7, 2024, the U.S. Senate Committee on Commerce, Science, & Transportation issued a press release about the proposed American Privacy Rights Act. "This comprehensive draft legislation sets clear, national data privacy rights and protections for Americans, eliminates the existing patchwork of state comprehensive data privacy laws and establishes robust enforcement mechanisms to hold violators accountable, including a private right of action for individuals." In short summary, the proposed law (i) establishes foundational uniform national data privacy rights for Americans, (ii) gives Americans the ability to enforce their data rights, (iii) protects Americans' civil rights, (iv) holds companies accountable and establishes strong data security obligations, and (v) focuses on the business of data, not Mainstreet business. Under the bill, covered data is "information that identifies or is linked or reasonably linkable, alone or in combination with other information, to an individual or a device that identifies or is linked or reasonably linkable to one or more individuals" residing in the US. Sensitive covered data includes, among other data, government identifiers. A covered entity under the bill is any entity that determines the purpose and means of collecting, processing, retaining, or transferring covered data and is subject to the FTC Act, including common carriers and certain nonprofits.

For additional information or for assistance with your organization's privacy and security program, contact:

Isabelle Bibet-Kalinyak, Vice Chair | 973.403.3131 | ibibetkalinyak@bracheichler.com
Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@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 Edward Hilzenrath and Counsel Colleen Buontempo.

EDWARD HILZENRATH

What is an interesting trend in Healthcare Law?

The consolidation of the healthcare industry has continued in 2024. Payers, hospitals and private equity roll-ups of medical practices continue to look for acquisition targets and strategic partners. While consolidation can lead to efficiencies and increased profits, there is new scrutiny from the Federal and State governments on the impact of consolidation on health care consumers.

What achievement are you most proud of?

I am most proud of when clients call me for follow up work or recommend me to their colleagues. It is tremendously gratifying to know when work we have done is impactful and valued by our clients and that they want to continue working with us and have their colleagues work with us as well.

COLLEEN BUONTEMPO

What is an interesting trend in Healthcare Law?

Currently, in the PIP realm of healthcare law, the current trend is whether low-speed vehicle (i.e. e-bikes, motorized scooters) accident victims are entitled to PIP coverage. There is a pending New Jersey Supreme Court decision in Goyco v. Progressive Insurance Company that could change the course of insuring these types of vehicles and covering the injuries sustained while operating them.

What achievement are you most proud of?

Graduating college. Common to a lot of people, but I am the only one in my immediate family to achieve a Bachelor's Degree. It inspired my pursuit of higher education.

On April 18, Healthcare Law Member **Carol Grelecki** moderated the 2024 Health Law Symposium. Sponsored by Brach Eichler and the Garden State Bar Association, the topics discussed included the impact of restrictive covenants, physician burnout, and healthcare transactions.

On April 1, Brach Eichler Managing Member and Healthcare Law Chair **John D. Fanburg** was quoted in an article for Modern Healthcare entitled "Change Healthcare breach already impacting healthcare M&A."

On March 25, Brach Eichler LLC announced the selection of 21 of the firm's attorneys for inclusion in the 2024 New Jersey "Super Lawyers" list. Congratulations to Healthcare law attorneys **Shannon Carroll**, **Paul J. DeMartino, Jr.**, **Lani M. Dornfeld**, **John D. Fanburg**, **Michael C. Foster**, **Joseph M. Gorrell**, **Carol Grelecki**, and **Cynthia J. Liba**.

BRACH EICHLER LLC
Counsellors at Law

Attorney Advertising: This publication is designed to provide Brach Eichler LLC clients and contacts with information they can use to more effectively manage their businesses. The contents of this publication are for informational purposes only. Neither this publication nor the lawyers who authored it are rendering legal or other professional advice or opinions on specific facts or matters. Brach Eichler LLC assumes no liability in connection with the use of this publication.

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

Colleen Buontempo, CPC | 973.364.5210 | cbuontempo@bracheichler.com
Paul J. DeMartino, Jr. | 973.364.5228 | pdemartino@bracheichler.com
Michael C. Foster | 973.403.3102 | mfoster@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com
Debra W. Levine | 973.403.3142 | dlevine@bracheichler.com
Erika R. Marshall | 973.364.5236 | emarshall@bracheichler.com

ASSOCIATES

Vanessa Coleman | 973.364.5208 | vcoleman@bracheichler.com

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