BRACH EICHLER LLC

NEW JERSEY ASSOCIATION OF AMBULATORY SURGERY CENTERS

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LEGAL REPORT

PRESENTED BY

JOHN D. FANBURG, ESQ.

I. COVID-19 LEGAL UPDATES

Brach Eichler has strived to keep abreast of the numerous legal developments that occurring during the nationwide novel coronavirus (COVID-19) public health emergency. Brach Eichler has created a COVID-19 Resource Center that consolidates our various important client alerts and webinar series information in one place. Please visit the Resource Center for updates at https://www.bracheichler.com/covid-19-resource-center/.

II. NEW JERSEY DEVELOPMENTS

A. Bill Introduced to Prohibit Medical Creditors from Reporting Medical Debt to Credit Reporting Agencies

On May 2, 2022, Bill A3802 was introduced in the New Jersey Assembly to prohibit medical creditors from reporting any portion of a medical debt which is alleged to be unpaid to any collection or credit reporting agency, bureau, or data collection facility. "Medical creditor" is defined as any health care provider that provides health care services and to whom the consumer owes money for health care services, or any person who purchases a debt arising from the receipt of health care services.

B. Bill Introduced to Limit Enforceability of Restrictive Covenants

On May 2, 2022, the New Jersey State Assembly introduced Bill A3715 seeking to regulate and limit in a multitude of ways the use of non-compete covenants in employment agreements. This Bill requires employers to provide 30 business days' notice of the terms of the non-compete, either before commencement of employment or before the agreement is to become effective. Additionally, it requires that restrictions be no broader than necessary to protect the employer's legitimate business interests. Notably, the Bill requires explicit written notice in the agreement that an employee has the right to consult with counsel before signing.

With respect to post-employment enforcement, the Bill limits the temporal scope of non-competes to 12 months following the date of termination. The Bill provides that restrictive

covenant agreements with employers cannot restrict an employee from performing work for a customer or client of the employer provided that the employee does not initiate or solicit the customer or client. The Bill also requires employers to provide notice of their intent to enforce the non-compete no later than 10 days after termination. Moreover, the Bill contains a provision that during any period after employment terminates, an employee is entitled to the pay such employee would have earned if not subject to terms of the restricted period as consideration for the non-compete. The new legislation, if enacted, would not apply retroactively to agreements entered into prior to the Bill's effective date. The Bill is pending review by the New Jersey Assembly Oversight, Reform, and Federal Relations Committee.

C. Governor Murphy Signs Executive Order 294, Clarifies Vaccine Requirements for Workers in Healthcare and Congregate Settings

On April 13, 2022, Governor Murphy signed Executive Order (EO) 294, clarifying that vaccination requirements for covered workers at healthcare facilities and high-risk congregate settings under EO 283 include only one booster dose of the COVID-19 vaccine and that a second booster is not required. Gov. Murphy nonetheless encouraged those who are eligible for the second booster to get the second booster, if eligible.

On March 2, 2022, Governor Murphy signed EO 290, revising timelines set forth in EO 283, which was signed on January 19, 2022. EO 283 required healthcare facilities and high-risk congregate settings covered by the EO to adopt and implement policies requiring covered workers to be up to date with their COVID-19 vaccinations, including having received a booster dose. EO 290 required the state timelines to align with updated CDC recommendations on optimal intervals between first and second doses of vaccination. Previously, EO 252, which was issued on August 6, 2021, required covered healthcare facilities and high-risk congregate settings to maintain policies that require covered workers to either provide proof that they have been fully vaccinated or be subject to COVID-19 testing at minimum one to two times per week. EO 283 eliminated the testing option that was previously allowed and required covered workers to be fully vaccinated, including a booster dose, while leaving intact the ability to grant exemptions for those with disabilities, medical conditions, or deeply held religious beliefs.

For purposes of EOs 294, 290 and 283, healthcare and high-risk congregate settings include facilities such as hospitals and licensed ambulatory care facilities. The EOs do not cover private physician offices; however, practitioners that render services at hospitals or other licensed facilities (including, but not limited to intermediate care facilities, ambulatory surgical centers, urgent are clinics, dialysis centers) covered by the EOs will be required to comply with the vaccination requirements of those facilities.

For purposes of EOs 294, 290, and 283, covered workers, including full and part-time employees, contractors and operational, custodial or administrative support, shall be considered "up to date" with his or her COVID-19 vaccinations if the worker has received a complete primary series and the first booster dose for which they are eligible, as recommended by the CDC.

- For covered healthcare settings that are covered by EOs 294, 290 and 283, and subject to the CMS Rule, all covered workers must have provided adequate proof

that they have received a booster dose by April 11, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

- For healthcare settings that are covered by EOs 294, 290 and 283, but not subject to the CMS Rule, and for covered high-risk congregate settings all covered workers must have provided adequate proof that they are up to date with their COVID-19 vaccination by May 11, 2022. However, as to having received a booster dose, covered workers must have provided adequate proof that they are up to date with their COVID-19 vaccinations by May 11, 2022, or within 3 weeks of becoming eligible for a booster dose, whichever is later.

EOs 294, 290 and 283 also require that covered workers currently subject to testing under EO 252 must continue once to twice weekly testing until they provide adequate proof that they are up to date with their vaccinations based on the respective applicable April 11, 2022 or May 11, 2022 deadline. Additionally, EO 283 requires covered settings to have a disciplinary process for noncompliance, including and up to termination of employment. Further, EO 290 requires a covered setting must take the first step toward bringing a noncompliant covered worker into compliance as part of the disciplinary policy within two weeks of the respective applicable April 11, 2022 or May 11, 2022 deadline. All covered settings should therefore be in compliance by the date of this Legal Update.

D. Hackensack Meridian Health and Englewood Health Withdraw Merger Plans

On April 5, 2022, Hackensack Meridian Health (HMH) and Englewood Health have terminated their hospital merger agreement. The decision comes after the U.S. Court of Appeals for the 3rd Circuit affirmed the order of a district court to block the deal on March 22, 2022.[1]

The health systems initiated the merger process when they signed a definitive agreement in October 2019. HMH had planned to acquire Englewood Health with an investment of $400 million. The Federal Trade Commission challenged the deal in 2020, arguing it would give HMH control of three of the six hospitals in Bergen County and raise healthcare costs. U.S. Circuit Judge D. Michael Fisher agreed the acquisition would raise price of hospital care in Bergen County and affirmed the lower court's decision.

E. Senate Passes Bill to Expand Health Care Professions Profiled under New Jersey Health Care Consumer Information Act

On March 24, 2022, the New Jersey Senate passed Bill S760 to expand the number of health care professions profiled under the New Jersey Health Care Consumer Information Act. The Bill is now being reviewed by the New Jersey Assembly. It would amend the Act by requiring the Division of Consumer Affairs to develop and maintain publicly accessible profiles of all health care professionals licensed by the Division. Currently, only physicians, podiatrists, and optometrists have such profiles. The Bill would also expand the information collected for the profiles, including (i) restrictions at New Jersey-based or out-of-State facilities; (ii) Medicare or

[1] Federal Trade Commission v. Hackensack Meridian Health Inc, No. 21-2603 (3d Cir. 2022).

Medicaid exclusions; and (iii) any actions taken by federal regulators such as the U.S. Food and Drug Administration or Drug Enforcement Agency.

F. Bill Introduced to Eliminate Certain Practice Restrictions for Advanced Practice Nurses

On February 7, 2022, the New Jersey State Assembly introduced Bill A2286 eliminating practice restrictions for advanced practice nurses (APNs), including restrictions that limit the ability of APNs to prescribe medications and administer anesthesia, and establishes new requirements for APNs to prescribe medications.

The Bill expressly provides that, notwithstanding the provisions of any other law or regulation to the contrary, an APN with greater than 24 months or 2,400 hours of licensed, active, advanced nursing practice will be authorized to practice without a joint protocol with a collaborating provider. The Bill further provides that every APN who is an APN-Anesthesia and who has completed 24 months or 2,400 hours of licensed, active, advanced nursing practice in an initial role will be authorized to practice as an APN-Anesthesia to the full scope of practice for APNs-Anesthesia, without any requirement for supervision by a licensed physician and without any requirement that the APN-Anesthesia enter into joint protocols with a licensed physician. Contrarily, an APN with fewer than 24 months or 2,400 hours of licensed, active, advanced nursing practice in an initial role will be permitted to prescribe medication only if a formal joint protocol with a physician or experienced advanced practice nurse is in place.

With regard to prescribing medications, the Bill requires the use of New Jersey Prescription Blanks and satisfying continuing professional education requirements related to pharmacology and prescribing controlled substances. Additionally, the Bill provides that any State law or regulation that requires the signature or similar endorsement of a physician will be deemed to require the same of an APN, to the extent consistent with an APN's scope of practice.

III. FEDERAL DEVELOPMENTS

A. DOJ Charges COVID Fraudsters Who Raked In Nearly $150 Million Through Elaborate Schemes

On April 20, 2022, the Department of Justice (DOJ) announced twenty-one (21) defendants were charged in nine (9) different districts related to over $149 million in COVID-19 related false billing issues. Over $8 million in cash and other fraud proceeds were also seized as part of these actions. Defendants included owners and executives of medical businesses, physicians, marketers, and manufacturers.

The announcement alleged several different COVID-19 health care fraud schemes, including: (i) laundering scheme that involved fraudulently billing over $214 million for laboratory tests, including more than $125 million for COVID-19 and respiratory pathogen tests; (ii) obtaining confidential patient information and samples from patients seeking COVID-19 testing at drive-thru testing sites and using that information to submit false and fraudulent claims for unrelated, medically unnecessary tests or in-office visits that did not occur; (iii)

billing for sham telemedicine encounters that did not occur; (iv) misappropriating funds from the Provider Relief Fund, intended to give financial assistance to medical providers providing medical care to Americans suffering from COVID-19; and (v) falsifying COVID-19 vaccination record cards to make it appear that customers received vaccines.

Collectively, the charges demonstrate DOJ's commitment to and focus on investigating and ultimately prosecuting alleged schemes that, in the agency's view, exploited the pandemic and the nation's public health emergency. These activities stem from the active work of the COVID-19 Fraud Enforcement Task Force, established in May 2021 to marshal resources to enhance efforts to combat and prevent pandemic-related fraud.

B. Georgia Anesthesia Group to Pay $7.2M over Kickback, False Claim Allegations

On April 13, 2022, the Department of Justice (DOJ) announced that the anesthesia management services company Care Plus Management (Care Plus) and its founders, along with 18 anesthesia entities that Care Plus owned and operated, will pay $7.2 million to settle allegations of kickbacks and false claims. The whistleblower for this case will receive over $1.3 million from the settlement under the False Claims Act.

Between 2012 and 2016, the founders of Care Plus allegedly convinced numerous ASC physician owners in Georgia, Florida, Texas, Alabama, and South Carolina to award exclusive service agreements in exchange for partial ownership in Care Plus anesthesia entities that would service the ASCs, particularly those ASCs specializing in gastroenterology, podiatry, and vascular surgery. Under these arrangements, the physician owners received compensation in the form of a portion of the revenue from the anesthesia services.

The Government further alleged that Care Plus subsidized the surgery centers' costs for drugs, supplies and equipment to further entice the physician owners to grant exclusive agreements to Care Plus. HHS-OIG has longstanding concerns about the provision of free or below-fair-market-value goods or services to an existing or potential referral source. Indeed, free or below-fair-market-value goods or services may be used as a vehicle to disguise or confer an unlawful payment for referrals of Federal health care program business. The Government alleged that such arrangements violated the Anti-Kickback Statute and caused the submission of false claims in violation of the False Claims Act.

C. No Surprises Act Update: New Arbitration Guidance May Give Doctors More Negotiation Room against Payers

On April 12, 2022, the Centers for Medicare & Medicaid Services (CMS) updated its surprise billing guidance to require independent dispute resolution entities (IDR Entities) to consider more than just the qualifying payment amount (QPA), the payer's median in-network contracted rate, when determining reimbursement amounts for out-of-network services under the federal No Surprises Act (NSA). This guidance comes in response to a Texas federal court decision that vacated parts of the independent dispute resolution (IDR) process set forth in the July 2021 interim final rule implementing some of the surprise billing prohibitions and restrictions.

The Texas court ruled that the initial regulations established under the No Surprises Act (NSA) improperly instructed arbitrators to presume that the QPA is the appropriate reimbursement amount. It was then up to the providers to rebut this presumption with other factors and convince the arbitrator to deviate from the QPA. The NSA enacted by Congress, however, did not give extra weight to the QPA. In affirming the lower court's decision, the Texas court of appeals' decision effectively stroke portions of the CMS regulations defining the IDR process.

The recently published CMS guidance provides that, in addition to the QPA, providers can submit other factors for the arbiter's consideration:

- The level of training, experience, and quality and outcomes measurements of providers or facilities;
- The regional market share held by the provider or facility;
- The acuity of the patient, member or enrollee receiving the service or the complexity of the service;
- The teaching status, case mix and scope of services the facility or provider offers; and
- The demonstration of good faith efforts, or lack of efforts, to enter into network contact agreements with one another

The guidance also states that IDR Entities, the licensed third party administrators of the IDR process, may not consider usual and customary charges for the service, the amount that providers would have billed without the NSA provisions, or the reimbursement rate for the service by public payers. The guidance also noted that it is not the IDR Entity's responsibility to determine whether the QPA is correct, make determinations of medical necessity, or review coverage denials.

In addition to the guidance highlighted above, CMS launched its long-anticipated online portal where healthcare providers and payers can initiate the IDR process. Parties may now use the portal to begin the process within four business days following the expiration of the 30-day negotiation period.

D. DOJ Issues Guidance on ADA Protection for Individuals Recovering From Opioid Use Disorder

On April 5, 2022, the Department of Justice (DOJ) published guidance explaining how the Americans with Disabilities Act (ADA) protects people who are in treatment or recovery for opioid use disorder (OUD), including those who take prescription medications as part of that treatment.

The guidance states that individuals in treatment or recovery from OUD are considered disabled under the ADA unless they are currently engaged in illegal drug use. These individuals may be prescribed medications such as methadone, buprenorphine, or naltrexone that are approved by the Food and Drug Administration (FDA). Employers may not discriminate against employees who are in treatment for OUD and who use such medications. Additionally, employees with a history of OUD have a "record of" a disability and are protected from discrimination. The ADA also protects from discrimination those who have a known association or relationship with someone who has a disability such as OUD.

Concerning employee drug testing, the guidance states that employers may test for illegal drug use. However, employers may not fire or deny employment to individuals legally using

medication prescribed for OUD, unless the use of such medication renders the individual unable to safely and effectively perform the job, or otherwise disqualifies them under another federal law.

E. OIG Approves Arrangement that Provides Cash Equivalents to Patients

On February 25, 2022, the Office of Inspector General (OIG) published an Advisory Opinion, approving a program through which a digital health company provides digital contingency management tools and incentives, including cash equivalents, to motivate behavioral health changes in individuals who suffer from substance use disorders. The program's services include appointment and medication reminders, saliva and breathalyzer testing, cognitive behavioral therapy, certified recovery coaching, and virtual support groups. The program provides incentives via a smart debit card that may not be used in certain locations, such as bars or liquor stores, when individuals complete certain events, such as attending a treatment session, or achieve certain behavioral goals, such as a negative substance test.

While individuals may self-enroll in the program, the company typically contracts with health plans, addiction treatment providers, and other providers that pay a flat monthly fee for each eligible member or select a pay-for-performance model under which they pay for achieving certain agreed-upon targets for abstinence. Each incentive payment is small, and annual incentive payments are capped at $599 annually per individual. The company itself is not enrolled in and does not receive remuneration from any federal healthcare program. Although the program is entirely digital, incentives may be tied to in-person services furnished by the company's customers, some of whom may bill federal healthcare programs for the in-person services they provide. The company certified to the OIG that the fees that is charges are consistent with fair market value and do not vary based on the volume or value of referrals.

The OIG noted that the proposed program included two streams of remuneration that could potentially violate the federal Anti-Kickback Statute (AKS) or the civil monetary penalty prohibition on federal beneficiary inducements (CMP), including the fee paid by customers for the program's services, some of which could incentivize a member to receive a federally billable service, and the incentive payments paid by the company, some of which may be paid to individuals for obtaining services that are billable to a federal health care program. The OIG reiterated its longstanding concerns about providing incentives to beneficiaries to obtain federally reimbursable services, which have the potential to lead to overutilization, patient steering, and increased costs. However, although neither remuneration stream satisfies the requirements of a safe harbor to the AKS or an exception to the CMP, the OIG found that this particular arrangement poses a minimal risk of fraud and abuse, since the incentives are part of an evidence-based treatment program rather than an inducement to seek federally reimbursable treatment, the program's incentives are relatively low in value, most of the incentives are not tied to federally payable services, and the company is not enrolled as a provider or supplier in any federal health care program.