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Health Law UPDATE

July 2019

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FEDERAL UPDATE

Dental Supplier Antitrust Litigation Settles for $80 Million

On June 24, 2019, the United States District Court for the Eastern District of New York approved an $80 million settlement in the antitrust class action case of *In Re Dental Supplies Antitrust Litigation*, No16-cv-00696. The plaintiff class was defined as anyone who purchased dental supplies and products directly from the defendants, Henry Schein, Inc., Patterson Companies, Inc., and Benco Dental Supply Company, from August 31, 2008 to March 31, 2016. The plaintiffs alleged that the defendants, three of the largest distributors of dental supplies and equipment in the United States, violated federal antitrust laws when they unlawfully agreed to not compete with one another and orchestrated barriers to prevent other competitors from entering the market. The plaintiffs argued that the dental suppliers acted in concert to inflate and fix prices on dental supplies and equipment, agreed to not solicit one another's customers, and boycotted manufacturers, dental associations, and other groups who engaged with the defendant suppliers' competitors. The alleged acts of the defendants left the plaintiffs with no option other than to maintain their relationships with the three suppliers in order to continue providing dental services to their patients.

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Erika Marshall | 973.364.5236 | emarshall@bracheichler.com
Cynthia J. Liba | 973.403.3106 | cliba@bracheichler.com

CMS Announces It Will Publish List of Poorest Performing Nursing Homes

Centers for Medicare & Medicaid Services (CMS) received recent backlash from two U.S. Senators, Bob Casey and Pat Toomey, about the agency's lack of transparency with the public about poor performing nursing homes.

CMS maintains a website, Nursing Home Compare (NHC), where it lists all U.S. nursing homes, along with a one- through five-star rating of each nursing home in three categories: health inspections, staffing levels, and quality measures. The health inspection ratings come from the on-site surveys conducted by state agencies when assessing compliance with CMS health and safety standards. The staffing levels rating is determined based on the number of nurses available at any given time. Quality measures are based on resident assessments and claims data sent to Medicare.

Senators Casey and Toomey, in their efforts to push CMS to provide greater transparency, noted that about half of the poorest performing nursing homes have at least three stars for staffing or quality ratings—evidence of a disconnect with the information published on the NHC website and the information available to CMS.

In addition to the ratings posted on the NHC website, which is accessible to the public, CMS maintains a list of the worst performing nursing homes eligible to become Special Focus Facilities (SFFs), facilities the federal government purports helps increase its ability to provide quality care.

There are currently only 88 nursing home SFFs, which Dr. Kate Goodrich, Director of the Center for Clinical Standards and Quality and CMS Chief Medical Officer, explains in her June 5, 2019 press release is a result of budget cuts. Still, CMS maintains a list of over 400 eligible nursing home candidates for this program, with eligibility based on extremely poor performance during health and safety inspections. This list is currently unavailable to the public.

For more information, contact:

Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Jocelyn Ezratty | 973.364.5211 | jezratty@bracheichler.com

A Bill to Protect Personal Health Data

On June 13, 2019, the Protecting Personal Health Data Act (S. 1842) was introduced in the Senate. The bill is a bipartisan effort, co-sponsored by U.S.Senators Amy Klobuchar and Lisa Murkowski, which seeks to bridge the gap between the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the increasingly technology-driven world.

HIPAA was enacted in the mid-1990s. Now, over two decades later, HIPAA is unable to offer adequate protection in the digital space. HIPAA only applies to "covered entities" and their "business associates," which typically does not include the operators of wearable fitness trackers, health-based social media sites, direct-to-consumer genetic testing, and the like. Moreover, reports show that operators use the information gathered from these platforms in ways that are likely unanticipated by consumers, thereby necessitating legislative intervention.

The Bill calls upon the Secretary of Health & Human Services (HHS), in consultation with the Chairman of the Federal Trade Commission (FTC) and others, to promulgate regulations to "strengthen privacy and security protections for consumers' personal health data that is collected, processed, analyzed, or used by consumer services, applications, and software." In doing so, the Bill lays out various considerations for the Secretary such as accounting for the "nature and sensitivity" of differing information and developing uniform standards for consumers to access their information. The Bill also provides for the establishment of a National Task Force on Health Data Protection to carry out responsibilities such as consulting, evaluating standards, and reporting on the effectiveness of regulations. The Bill has been referred to the Committee on Health, Education, Labor, and Pensions (HELP).

For more information, contact:

Lani M. Dornfeld, CHPC | 973.403.3136 | ldornfeld@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Amy F. Eng | 973.403.3143 | aeng@bracheichler.com

New Federal Rule Expands Use of Health Reimbursement Arrangements

On June 13, 2019, the Departments of Health & Human Services, Treasury, and Labor released a final rule permitting employers, beginning in 2020, to use Health Reimbursement Arrangements (HRAs) to reimburse employees for individual market health insurance premiums. An HRA is a tax-favored group health plan funded solely by employer contributions that reimburses an employee for medical care expenses incurred by the employee or the employee's spouse, dependents, or children who have not attained age 27 as of the end of the taxable year. Employee reimbursements are capped by a maximum dollar amount for a coverage period. Prior to the rule, HRAs were not permitted under the Patient Protection and Affordable Care Act for this purpose because it did not comply with statutory requirements regarding essential benefits. The new rule will give employers, particularly small businesses, significant options for financing health insurance coverage.

The Departments announced that they expect 800,000 employers to provide HRAs to pay for individual health insurance coverage for approximately 11 million workers and their families, including nearly 800,000 who are currently uninsured. The final rule includes provisions to mitigate the risk of adverse selection in the individual market and to ensure employees understand how HRAs work.

In addition to allowing individual coverage HRAs, the rule also creates an "excepted benefit" HRA. This type of HRA allows employers that offer traditional group health plans to provide a benefit of up to $1,800 per year (indexed to inflation after 2020), even if the employee does not enroll in the traditional group health plan, and to reimburse an employee for certain qualified medical expenses. This provision is attractive to employees who have opted out of their employer's traditional group health plan because the employee contribution towards premiums is too expensive.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Joseph M. Gorrell | 973.403.3112 | jgorrell@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

Courts Order Delay of Conscience Rule

Federal judges in two of the lawsuits filed against the Trump administration to block the final conscience rule from taking effect have ordered that the rule be delayed until November 22, 2019. The rule was originally set to take effect on July 22, 2019. As reported in last month's *Health Law Update*, the Department of Health & Human Services (HHS) Office for Civil Rights released, in May, the final conscience rule that protects federally funded health care entities, professionals, and employees who have conscience or religious objections related to performing, paying for, referring for, providing coverage of, or providing certain services, including but not limited to, abortion, sterilization, or assisted suicide. In separate lawsuits led by the State of California and the State of New York, HHS agreed to court orders delaying implementation of the rule until November while the merits of the cases are heard by the courts.

For more information, contact:

Riza I. Dagli | 973.403.3103 | rdagli@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Susan E. Frankel | 973.364.5209 | sfrankel@bracheichler.com

STATE UPDATE

New Jersey Legislative Update

Proposed Patient Protection Act Passed by New Jersey Assembly – On May 23, 2019 the New Jersey Assembly passed Bill A5369, the "Patient Protection Act," which establishes requirements concerning the transfer and referral of certain patients receiving health care services. The New Jersey Senate has not yet held a final vote on the Bill. Supporters of the Bill believe it is necessary to close a loophole in the Out-of-Network Consumer Protection, Transparency, Cost Containment and Accountability Act (the Act) due to a lack of transparency when patients are transferred for out-of-state care and out-of-network charges are applied in the other state. The Bill requires health care professionals, prior to obtaining consent to transfer a patient to a health care facility located outside of New Jersey, to provide the patient, in writing and in a manner that is easily understood, and also document in the patient record, the following information: (i) the patient's right to receive medical care at a health care facility of the patient's choosing; (ii) the clinical basis for the patient's proposed transfer to a health care facility located outside the State; (iii) the availability of clinically appropriate services at health care facilities within the State or a determination that no such clinically appropriate services are available in the State; (iv) in the case of a trauma-related, stroke-related, or cardiovascular-related diagnosis, a determination as to why the patient is not being transferred to a Level 1 or Level 2 trauma center, designated certified comprehensive or primary stroke center, or a licensed State cardiac surgery center, as appropriate; and (v) if the health care facility is affiliated with the out-of-State facility, the nature of the relationship between the facilities.

BME Continuing Medical Education Rules Revised to Include Opioid Education – Effective June 3, 2019, the New Jersey Board of Medical Examiners continuing medical education rules have been revised to include an opioid education requirement. For physicians, commencing with the biennial renewal period beginning on July 1, 2017, one of the 40 credits in Category I courses is required to be in programs or topics concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion. For physician assistants, commencing with the biennial renewal period beginning on September 1, 2017, one of the 50 continuing education credits is required to be in programs or topics concerning prescription opioid drugs, including responsible prescribing practices, alternatives to opioids for managing and treating pain, and the risks and signs of opioid abuse, addiction, and diversion.

Physical Therapy Rules Adopted Regarding Wound Debridement and Supervision Standards – Effective June 3, 2019, the State Board of Physical Therapy Examiners rules were revised regarding wound debridement and supervision standards in order to enable P.L. 2017, c. 121, which expanded the scope of practice for licensed physical therapists to include wound debridement and revised supervision standards for licensed physical therapists and licensed physical therapist assistants. Prior to performing wound debridement, a licensed physical therapist must communicate with a patient's physician or podiatric physician and document such communication in the patient records. With regard to supervision, licensed physical therapist assistants may provide services under direct or general supervision. A licensed physical therapist shall not provide general

supervision of a licensed physical therapist assistant until the licensed physical therapist has practiced, either in New Jersey or in another state, for at least one year. In addition, a licensed physical therapist shall ensure that a licensed physical therapist assistant has worked, either in New Jersey or in another state, for at least one year prior to providing general supervision of that licensed physical therapist assistant.

State Licensing Boards Propose Telemedicine and Telehealth Regulations – On June 17, 2019, the New Jersey State licensing boards that regulate physical therapists, midwives, athletic trainers, genetic counselors, psychologists, psychoanalysts, orthotists, and prosthetists, released proposed regulations to implement New Jersey's telemedicine and telehealth statute, which became law on July 21, 2017. The proposed regulations from each board were substantially similar to one another as well as to the proposed regulations for physicians, which were released on May 6, 2019. The proposed regulations set forth requirements for the practice of telemedicine and telehealth in New Jersey by the various licensees listed above, including in the following areas:

- The required standard of care to practice telemedicine and telehealth
- The establishment of a licensee-patient relationship
- The requirements for providing services through telemedicine and telehealth
- Recordkeeping
- The prevention of fraud and abuse
- Privacy and notice to patients

Comments on the proposed regulations must be submitted to each licensing board by August 16, 2019.

Out-of-Network Notification Bill Passed – On June 20, 2019, the New Jersey Assembly and the New Jersey Senate passed Bill A5363, which required carriers that offer health benefits plans to provide new or existing subscribers with notification of certain hospital and health system contract expirations. The Bill, which now awaits Governor Murphy's signature, provides that any carrier that offers a health benefits plan is required to provide written notification to each subscriber at least 90 business days prior to the termination, withdrawal, or severance of any hospital or health system contracts from the carrier's network. In addition, prior to enrolling, the carrier must inform a prospective subscriber of any hospital or health system contract in effect at the date of enrollment and any hospital or health system contract which will terminate or sever 90 days or less after the subscriber's effective enrollment date in that health benefits plan.

Board of Nursing Proposes New Electronic Prescription Rules for APNs – On June 17, 2019, the Board of Nursing (BON) released proposed regulations to authorize advance practice nurses (APNs) to transmit an electronic prescription to a pharmacy. The electronic prescription must contain the information required by the BON regulations, except that an electronic prescription need not contain a handwritten original signature. The proposed regulations impose additional requirements when an APN transmits electronic prescriptions for Schedule II, III, IV, or V controlled substances. Comments on the proposed regulations must be submitted by August 16, 2019.

Board of Nursing Proposes Rules Regarding Dispensing Maintenance or Detoxification Treatment Drugs – On June 17, 2019, the Board of Nursing released proposed regulations which would permit advanced practice nurses (APNs) to dispense narcotic drugs for maintenance or detoxification treatment if the APN has met the training requirements of, and is registered pursuant to, subsection (G) of 21 U.S.C. § 823, which sets forth the registration requirements for practitioners to dispense narcotic drugs. An APN may dispense the drugs even if his or her collaborating physician has not met the requirements of subsection (G) of 21 U.S.C. § 823, as long as the joint protocol between the APN and the collaborating physician includes the physician's written approval for the dispensing of such drugs. Comments on the proposed regulations must be submitted by August 16, 2019.

New Law Authorizes Creation of State-Based Exchange for Health Insurance Plans – On June 28, 2019, Governor Phil Murphy signed into law Bill A5499, which authorizes the Department of Banking and Insurance (DOBI) to establish, operate, and fund a State-based exchange for certain health benefits plans. Specifically, the Bill establishes a non-lapsing revolving fund to be known as the "Individual Health Insurance Exchange Trust Fund." The fund will be the repository for money collected pursuant to the Bill and other money received as grants or otherwise appropriated for the purposes of supporting health insurance outreach and enrollment efforts through an exchange. The fund will be used to support the exchange through initial start-up costs, exchange operations, outreach, enrollment, and other means, including any efforts that can increase market stabilization and that result in a net benefit to policyholders. The Bill allows the DOBI Commissioner to apply a monthly assessment to each individual health benefits plan sold in the individual market in New Jersey to raise money for the fund.

For more information, contact:

John D. Fanburg | 973.403.3107 | jfanburg@bracheichler.com
Carol Grelecki | 973.403.3140 | cgrelecki@bracheichler.com
Keith J. Roberts | 973.364.5201 | kroberts@bracheichler.com
Ed Hilzenrath | 973.403.3114 | ehilzenrath@bracheichler.com

Brach Eichler In The News

John D. Fanburg was named #6 on *NJBIZ'* list of its Power 50 in the Law.

Lani M. Dornfeld addresses attendees of the Home Care of Florida's annual conference, Home Care Con, on "HIPAA Breach Response, Investigation and Reporting: How to Follow the Rules to Reduce Fines and Penalties (and What the Rules Don't Say, but You Need to Know)", July 31.

In an Op-Ed for *ROI-NJ* on July 8, **John D. Fanburg** provided insight on the benefits of New Jersey's expanded medical marijuana program.

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

New Jersey Healthcare Market Review

Join Brach Eichler's healthcare law attorneys and an outstanding group of speakers, including keynote speaker RWJBarnabas Health President and CEO Barry H. Ostrowsky, for our tenth annual **New Jersey Healthcare Market Review (NJHMR).** The conference will be held September 18 - 19 at the Borgata in Atlantic City. Register today! Visit www.njhmr.com for more information.

HIPAA CORNER

Quest Diagnostics and LabCorp Face Lawsuits Over Data Breaches Affecting Millions

Law360 reports that both Quest Diagnostics (Quest) and LabCorp disclosed data breaches in early June (just one day apart from each other), affecting nearly 12 million and 8 million of their patients, respectively. Personal data was exposed as a result of a cybersecurity incident at a third-party billing collections vendor used by both medical testing providers.

The vendor, American Medical Collection Agency (AMCA), provides services to LabCorp and to one of Quest's revenue-cycle contractors, Optum 360. AMCA notified Quest, Optum 360, and LabCorp that an unauthorized user had accessed the company's web payment system. The Quest and LabCorp data breaches included some demographic and financial information but no laboratory test results. Unfortunately, for Quest it also included Social Security numbers and medical information.

AMCA has yet to provide Quest or LabCorp with a list of affected patients or detailed information about the data security incident. LabCorp, like Quest, has suspended sending collection requests to AMCA. AMCA said it was taking steps to increase the security of its systems, including migrating its web payment portal services to a third-party vendor. It is also working with outside experts to improve its security.

Quest has since been hit with a putative class action in New Jersey federal court accusing it of breaching its implied contract with patients, being negligent, and violating the Massachusetts Consumer Protection Act by failing to protect patient information.

Similarly, LabCorp is being sued by patients who filed a proposed class action in New York federal court accusing it of failing to protect their financial, medical, and personal information and for failing to report the incident or warn victims in a timely manner.

In addition, *Modern Healthcare* reports that as a result of these incidents, two Democratic state attorneys general have launched an investigation into AMCA's massive data breach. They are requesting that AMCA, LabCorp, and Quest each provide information on the number of residents affected by the breach, as well as a description of how the companies plan to protect patients whose personal data was exposed. They are also investigating how the data breach persisted for nearly eight months, what measures the three companies had in place to protect patient privacy prior to the incident, and what plans they have implemented since to prevent future data breaches.

Changes to Privacy Rules for Opioid Treatment Records May be Under Review

Bloomberg Law reports that next month, the U.S. Department of Health & Human Services plans to release a proposed rule amending the federal substance use disorder treatment records privacy law found at 42 C.F.R. Part 2. These federal rules protect the privacy of patients seeking, undergoing, or having undergone substance use disorder treatment at a program covered by the regulations. In many respects, the regulations are more stringent than HIPAA, especially with respect to disclosures among treating providers. It is anticipated the proposed rule will "remove barriers to coordinated care and permit additional sharing of information among providers and Part 2 programs assisting patients with substance use disorders." The proposal is undergoing review at the Office of Management and Budget. We will continue to monitor the progress of the rule proposal.

If you need assistance in reviewing your policies and procedures, managing a breach incident, or fulfilling any required reporting, please contact:

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

Healthcare Law Practice | 101 Eisenhower Parkway, Roseland, NJ 07068 | 973.228.5700

Members

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

Counsel

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

Associates

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

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