BRACH | EICHLER LLC

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2017 Health Law Year in Review

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The Brach Eichler Health Law Practice Group is pleased to provide its ninth annual Year in Review. The 2017 Year in Review highlights key issues and developments at the state and federal level concerning health care providers over the past 12 months.

As always, if you have any questions or would like additional information regarding any of the articles contained in the 2017 *Year in Review*, please do not hesitate to contact John D. Fanburg, Esq., Chair of Brach Eichler's Health Law Practice Group.

OIG Allows Free Meals and Lodging Under Affordable Care Act "Exception"

On March 3, 2017, the United States Office of the Inspector General (OIG) issued a favorable advisory opinion regarding a hospital's proposal to provide free or reduced-cost lodging and meals to certain financially needy patients. The opinion specifically addressed whether the program would violate the federal Anti-Kickback Statute (AKS). The OIG concluded that the proposal would not violate the AKS, because it meets an exception recently established by the Affordable Care Act that allows the financial benefit to be provided if it improves a beneficiary's ability to obtain services payable under Medicare or Medicaid, and poses a low risk of fraud and abuse.

In the specific case reviewed by OIG, the system hospital operates a Level 1 trauma center and provides state-of-the-art treatment to patients who reside in rural and medically underserved areas. The program would be limited to modest hotels and hospital cafeteria meals. To qualify for the program, the patient must reside 90 miles or more from the hospital and in a medically underserved or a health professional shortage area, as defined under the Public Health Service Act; the patient's household income cannot exceed 500% of the federal poverty level; and the patient's treatment must warrant the hotel stay. Based on those facts, the OIG found that the exception applied. The decision suggests that other medical providers may now have flexibility in designing similar programs to promote access to care.

NJ Appeals Court Explains Hospital Self-Critical Analysis Privilege and Reporting Duties

A New Jersey appeals court ruled on February 6, 2017 that a hospital defending a medical malpractice case was not required to give the patient an internal hospital memo reviewing the event. The court found that the memo was privileged since it was made as part of the hospital's "self-critical analysis" in developing and implementing a patient safety plan, as provided in the Patient Safety Act (PSA). The privilege applied even if the hospital did not report the event to the New Jersey Department of Health or the patient. The case is *Brugaletta v. Garcia, 448 N.J. Super. 404 (App Div. 2017)*.

The court also ruled that the hospital did not violate its obligation under the PSA to report a "serious preventable adverse event." No "preventable" event was proven, because the patient did not show that the event could have been anticipated and prepared for in advance.

The case demonstrates that while the PSA places many safety requirements on hospitals, it also provides hospitals with substantial protections, when they engage in self-critical analysis to promote patient care.

Amendments to NJCLIA

On January 9, 2017, Governor Christie signed into law certain amendments to the New Jersey Clinical Laboratory Improvement Act (CLIA) which went into effect immediately. As a result of extensive pressure from certain advocacy groups in search of a better understanding of these amendments, and their effect on the provision of clinical laboratory services in New Jersey, the New Jersey Department of Health Clinical Laboratory Improvement Service (CLIS) issued a guidance memorandum on April 10, 2017. The memorandum details the CLIA amendments and how CLIS intends to implement the changes, pending official revision to its implementing regulations. In short, the guidance memorandum details the following:

- CLIS licensure is not required for facilities that perform only point of care laboratory testing so long as certain criteria are met such as where instruments or kits are used, place of testing, type of tests, management and quality controls
- Quality control program standards will not exceed the standards set forth in federal regulations, or alternative quality control testing procedures approved by Centers for Medicare & Medicaid Services
- CLIS must recognize all waived tests under the federal "Clinical Laboratory Improvement Amendments of 1988" (FCLIA), as well as require that standards for use of such waived tests not exceed the FCLIA standards, so long as CLIS by way of CLIA, or with additional amendments to CLIA, determine it necessary to protect the public health
- Collection station licensure is required for NJ schools that collect patient specimens and refer such specimens to reference laboratories
- Collection stations require CLIS licensure even if a certificate of waiver is obtained
- CLIS maintains authority to investigate all clinical laboratories and collection stations
- Anatomic pathology is within the scope of practice of a clinical laboratory, thereby requiring licensure by CLIS.

New Jersey Supreme Court Rejects Sham Physician Ownership of Multidisciplinary Medical Practices

On May 4, 2017, the New Jersey Supreme Court imposed liability under the New Jersey Insurance Fraud Prevention Act (IFPA) on a chiropractor and an attorney for knowingly helping a chiropractor create an unlawful multidisciplinary practice in violation of rules governing the supervision and ownership of a medical practice. In the case, Allstate Insurance Company v. Northfield Medical Center, P.C., 2017 WL 1739692, *Allstate alleged that the defendants knowingly assisted and encouraged an investing chiropractor to retain control of the finances of a medical practice. Allstate claimed this violated a state rule, N.J.A.C. 13:35-6-16, which provides that a medical doctor may not be employed by a licensee with a more limited scope of practice, such as a chiropractor.*

The Use of Management Companies

The use of management companies and management services agreements is an acceptable way to manage the business aspects of a medical practice, as long as they do not have a fundamental impact on the delivery of health care services. State regulations do not preclude administrative services agreements between a management company and a professional medical practice and New Jersey courts have approved such a relationship. However, the rules and court decisions make clear that medical doctors must always maintain and exercise professional judgment in rendering professional services and must not be subject to undue influence or control by others.

What Went Wrong in This Case?

In this case, the court agreed with Allstate that the defendants — including a chiropractor and an attorney — intentionally promoted what they knew was a "lie"— a business model that appeared to have medical doctors supervising and controlling a medical practice, but that actually placed control in the hands of a chiropractor through deceptive efforts at "shielding the true controller." These tactics included listing medical doctors as the "owners" but who never treated patients of the practice. The "owners" also were required to sign agreements allowing the chiropractor to remove the doctor-owners from their positions. In addition, insurance

fraud was involved because the illegal practice structure caused the claims to insurance companies to be ineligible for payment, and fraudulent. The court found that the defendants knew they were violating legal rules on medical practice ownership and supervision, and committed fraud by trying to hide their actions from detection.

Takeaways

The decision in this case is important for several reasons. First, courts will enforce the rule that medical practices must be owned and controlled by fully licensed medical doctors, not just on paper but in reality. Second, any person, including a health care or business professional, who knowingly attempts to violate rules concerning New Jersey ownership and operation of medical practices, is subject to liability for fraud. Insurance companies such as Allstate are ready to file fraud suits in such cases. Since violations of the IFPA result in triple damages and awards of attorneys fees to insurance companies, medical professionals should carefully review their practice structures and management agreements.

New Jersey Board of Nursing Adopts Rules Amendment for Dispensing Medication

The New Jersey Board of Nursing has amended its rules governing dispensing of medications. The rule now requires advanced practice nurses who dispense pharmaceutical samples to patients to label such samples with the following: (i) the complete name of the medication dispensed; (ii) the strength and quantity of the medication dispensed; (iii) instructions as to the frequency of use; (iv) any special precautions; and (v) the expiration date of the medication. All of this information must be included on each label placed on a sample. Advanced practice nurses are not required to label samples when manufacturers have already included this information. However, if any of the required information is missing on a sample, the nurse must supplement the sample with the necessary information. The regulation is located at N.J.A.C. 13:37-7.10.

Government Intervenes in Whistleblower Suit Against MRI Provider

On January 29, 2018, the U.S. District Court for the District of Delaware entered a $16.2 million judgment against Orthopaedic and Neuro Imaging LLC (ONI) for submitting false claims for Medicare reimbursement. Under the terms of the judgment, ONI's owner, Richard Pfarr, is jointly and severally liable for $6.1 million.

In September 2017, the federal government intervened in the whistleblower action against ONI under the federal False Claims Act (FCA). *U.S. ex rel. White v. Orthopaedic and Neuro Imaging LLC et al., No. 1:13-cv-01109* (U.S. District Court, District of Delaware). The lawsuit, originally filed under the *qui tam* provisions of the federal FCA, was brought by a former employee who worked as an MRI technologist for ONI. The Court granted the government's request for default judgment on its complaint, which alleged that ONI and Pfarr knowingly submitted false claims to Medicare by administering contrast dye during magnetic resonance imaging (MRI) scans on patients without proper supervision by a physician. Contrast dye is a chemical that is injected intravenously into the body in order to make certain tissues more clearly visible on an MRI.

Medicare covers reasonable and necessary diagnostic radiology tests so long as the tests are properly supervised by a physician. A contrast MRI requires direct supervision, meaning a doctor must be present in the office and immediately available if required. The lawsuit accused ONI of billing Medicare for thousands of contrast dye injections performed without proper supervision, despite Pfarr signing an acknowledgement that he understood Medicare's requirements. The case serves as a reminder that providers must ensure appropriate supervision requirements are met under Medicare and other laws and rules.

New Jersey Dentists May Bill for Diabetes Screening

As of January 1, 2018, New Jersey dentists can bill for performing chair-side diabetes screenings for at-risk patients. The screening is a finger-stick capillary HbA1c glucose test procedure that can be used to rapidly identify high-risk patients.

In January 2015, the New Jersey Board of Dentistry ruled that administering blood sugar screenings was within a dentist's scope of practice. The Board also held that such screenings are not, however, presumed to be the standard of care. In response to the Board's ruling, Delta Dental of New Jersey launched a pilot program to enable network providers to screen for diabetes and encourage appropriate referrals. New Jersey is at the forefront of a movement to use dentists as part of a coordinated effort to diagnose and treat diabetes.

Effective as of 2018, the American Dental Association (ADA) developed a new dental procedure billing code to address the testing, which opens the door for reimbursement requests. D0411 is defined as "HbA1c in-office point of service testing." The ADA also published guidance on point of care for diabetes testing and reporting that includes the following:

- When a screening test should be recommended,
- How the procedure is delivered,
- How to analyze the results, and
- What to do with the test results.

Dentists interested in providing the testing must ensure they have the appropriate lab licensing and related safeguards in place. In addition, the Board has held that if the screening is provided, then the results should be provided to the patient and appropriate referrals made.

Telemedicine Bill Adopted in New Jersey

On July 21, 2017, then-Governor Chris Christie signed into law bill S291 to define and regulate the practice of telemedicine in New Jersey. The bill authorizes health care providers, including licensed physicians, nurses, nurse practitioners, psychologists, psychiatrists, psychoanalysts, clinical social workers, physician assistants, professional counselors, respiratory therapists, speech pathologists, audiologists, and optometrists, to remotely provide health care services to patients through the use of telemedicine.

Under the bill, health care providers will be permitted to remotely provide health care services to a patient through the use of telemedicine, and will be permitted to engage in telehealth as may be necessary to support and facilitate the provision of health care services to patients. Health care providers engaging in telemedicine must: (1) be validly licensed, certified, or registered to provide such services in the State of New Jersey; (2) remain subject to regulation by the appropriate New Jersey state licensing board or professional regulatory entity; (3) act in compliance with existing requirements regarding the maintenance of liability insurance; and (4) remain subject to New Jersey jurisdiction if either the patient or the provider is located in New Jersey at the time services are provided. Medicaid, NJ FamilyCare, and certain other health insurance providers, including the carriers of health benefits plans, will be required to provide coverage and payment for services provided through telemedicine on the same basis as, and at a provider reimbursement rate that does not exceed the provider reimbursement rate that is applicable, when the services are delivered in-person.

New Jersey Tackles Opioid Crisis

On February 15, 2017, then-Governor Chris Christie signed into law a bill that limits prescriptions by physicians for opioid painkillers and requires insurance carriers to cover treatment for addiction and substance use disorders. Under the new law, the strictest on opioid prescription in the country, a five-day limit is imposed on initial prescriptions for opioids. The law contains certain exceptions, such as for cancer or hospice patients. Previously, the limit in New Jersey was a 30-day supply.

The law also requires insurers to cover up to 180 days of drug treatment for patients, including both outpatient and inpatient treatment. In addition, insurers

may not impose utilization review or management requirements on treatment or prior approval requirements for covered medication-assisted treatments. Insurers also must not impose prepayment obligations and may only charge a plan's regular copayments, deductibles, and co-insurance for substance use disorder treatment.

The law also requires the state to provide monitoring in order to prevent fraud or abuse and to ensure that providers are not improperly treating patients who do not actually require substance abuse treatment. The new drug treatment mandate does not apply to insurance programs that are not subject to state regulation, such as Medicare or large-employer plans.

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