BRACH EICHLER LLC

NEW JERSEY ASSOCIATION OF AMBULATORY SURGERY CENTERS

JUNE 14, 2017

ANNUAL MEETING

LEGAL REPORT

PRESENTED BY

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I. NEW JERSEY DEVELOPMENTS

A. New Jersey Supreme Court Rules Against Non-Physician Controlled Medical Practice

In the case of *Allstate Insurance Co. v. Northfield Medical Center, P.C.*, the New Jersey Supreme Court on May 4, 2017 reinstated a $4 million judgment awarded to Allstate Insurance Company ("Allstate") and held that an attorney and a consultant knowingly violated New Jersey state law, specifically the Insurance Fraud Prevention Act, by assisting a chiropractor in setting up an unlawful medical practice that submitted claims to Allstate. The Court held that it is improper for a medical practice to allow a chiropractor to effectively own and control a medical practice. "Defendants extensively promoted a professional practice structure that a fact-finder could reasonably conclude was little more than a sham intended to evade well-established prohibitions and restrictions governing ownership and control of a medical practice by a non-doctor," Justice LaVecchia wrote in the unanimous opinion.

In light of the Supreme Court's holding, many management company models for structuring practices could be considered suspect and subject to liability, including the following:

- Arrangements where a management company exercises control over a physician by virtue of being able to hire or fire the physician, control the medical practice's finances or ability to practice, including, for example, through leases, management agreements and/or equipment leases.

- Arrangements where a physician serves as the owner of the practice, is paid a salary versus a profit distribution, while the management company sweeps the practice's accounts of all remaining profits.

B. New Jersey Seeks to Revoke Psychologist's License over Patient Disclosures

On April 7, 2017 the New Jersey Attorney General filed a complaint with the New Jersey Board of Psychological Examiners to revoke or suspend the license of Barry Helfmann, a prominent New Jersey psychologist with a practice based in Springfield, New Jersey. The suit alleges that Dr. Helfmann violated New Jersey Board of Psychological Examiners patient confidentiality regulations due to his failure to take reasonable measures to protect the confidentiality of clients' protected health information. Dr. Helfmann and his practice, Short Hills Associates, permitted details of patients' mental health treatments to be disclosed in lawsuits over unpaid bills.

The suit by the New Jersey Attorney General follows the disclosure last year that Short Hills Associates had filed 24 collection cases between 2010 and 2014 where patient names, diagnoses and treatments were disclosed. The Health Insurance Portability and Accountability Act (HIPAA) generally allows health providers to sue patients to collect unpaid debts, but requires the providers to only disclose the minimum information necessary to pursue the suit. In March 2015, a patient filed a complaint with the Office for Civil Rights of the federal Department of Health and Human Services (OCR) alleging that the disclosure of his diagnoses and treatments by Short Hills Associates was a violation of HIPAA. However, the OCR closed the case with no action taken because Short Hills Associates was not considered a HIPAA-covered entity at the time because HIPAA only covers providers who submit data electronically, and Short Hills Associates did not submit data electronically at the time of the disclosures.

Dr. Helfmann has disputed the allegations against him and Short Hills Associates, stating in a recent interview that he relied on the expertise of his lawyers in pursuing patient payments. He filed a legal malpractice case against the collection law firm, Rothbard, Rothbard, Kohn & Kellar.

C. DOH Adopts Regulations Implementing Health Care Professional Responsibility and Reporting Enhancement Act

The New Jersey Department of Health (DOH) recently adopted regulations that implement portions of the Health Care Professional Responsibility and Reporting Enhancement Act (HCPRREA). The HCPRREA, which was passed in 2005, created a Health Care Professional Information Clearing House under the auspices of the New Jersey Division of Consumer Affairs, and requires New Jersey health care entities, including licensed ambulatory care facilities, to notify the Clearing House Coordinator regarding a health care professional's conduct relating to impairment, incompetence or professional misconduct which relates to patient safety, and the actions that the health care entity has taken against the offending health care professional. The new DOH regulations are in addition to, and are meant to be applied consistent with, regulations regarding the HCPRREA that were previously adopted by the New Jersey Division of Consumer Affairs (DCA).

Under the new DOH regulations, a health care entity is required to comply with the DCA regulations regarding reporting to the Clearing House Coordinator and is required to use the form of report adopted in the DCA regulations. The new DOH regulations also set forth rules regarding how health care entities inquire about health care professionals, including standardized forms to use for such inquiries, as well as how healthcare entities respond to an inquiry. In addition, the new DOH regulations require health care entities to maintain a record of all reportable events for a minimum of seven years. Finally, under the new DOH regulations, a

health care entity may be subject to fines ranging between $250 and $1,000 for various violations of the new DOH regulations.

D. Bill Seeks to Protect People with Preexisting Conditions

On May 8, 2017, Senate Bill 3158 was introduced to bar health insurance companies from excluding coverage, imposing waiting periods or raising premiums for people with preexisting conditions. On May 22, 2017, an identical Assembly Bill was introduced (A4877). The bill provides that a health insurer cannot impose, or include in its insurance policies, any provision excluding coverage for a preexisting condition. In addition, an insurer cannot include any preexisting condition as a factor in calculating premiums.

While the federal Affordable Care Act (ACA) mandates that health insurers, except in certain grandfathered plans, cannot include an exclusion for a preexisting condition in any insurance policy, New Jersey law was never changed to conform to the ACA. The bill revises New Jersey law to conform to the ACA regarding preexisting conditions. It is the sponsor's intent that, if the ACA is ever amended or repealed, the prohibition on insurers excluding coverage for preexisting conditions, putting certain waiting periods on coverage, or using a preexisting condition as a factor in setting premiums, would continue to be prohibited in New Jersey.

E. Pharmaceutical Sample Regulations Amended for Advanced Practice Nurses

N.J.A.C. 13:37-7.10 "Requirements for Dispensing Medications" has been amended to require 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 manufactures have already included this information, however, if any of the above information is missing on a sample, a nurse must supplement the sample with the necessary information. The Board of Medical Examiners requires physicians to comply with similar labeling requirements.

II. FEDERAL DEVELOPMENTS

A. DOJ Joins FCA Case Involving Medicare Advantage

The Department of Justice (DOJ) intervened in a qui tam suit against UnitedHealth Group, Inc. (UnitedHealth) filed in a California federal court on May 1, 2017. The DOJ's intervention marks its first False Claims Act complaint in a whistleblower led suit alleging Medicare Advantage Fraud. In its complaint, the DOJ alleges UnitedHealth systematically ignored information in failing to investigate unsubstantiated diagnoses of patients to boost its "risk adjustment" payments. Specifically, the government alleges that UnitedHealth conducted "one-sided" chart reviews that focused only on maximizing government payments, and neglected to correct errors that lead to overpayments. The DOJ indicated it intends on intervening in another similar case filed by a former UnitedHealth executive alleging UnitedHealth wrongly received at least $1 billion in risk adjustment payments.

In Medicare Advantage plans, the government pays health insurers, like UnitedHealth, a per-member, per-month payment for beneficiaries. A higher fee is provided for beneficiaries who have a higher risk score in anticipation of higher health care costs. However, program rules require that information must be submitted in support of a patient's medical record to justify the higher fee. The DOJ alleges UnitedHealth knew that a significant portion of the claims reported were invalid because the beneficiaries' medical records did not support the medical conditions. UnitedHealth intends to contend the government's claims "vigorously".

It is estimated that billions of dollars in unsupported risk adjustment payments are paid out each year. Earlier this year, the DOJ disclosed it currently has ongoing investigations regarding risk adjustment practices at other carriers, including Aetna and Cigna, suggesting a new trend in FCA litigation.

B. Texas Health System Enters $2.4M Settlement for Potential HIPAA Violations

Memorial Hermann Health System (MHHS), a not-for-profit health system based in Houston, Texas, has entered into a resolution agreement with the Department of Health and Human Services Office for Civil Rights to pay $2.4 million and adopt a corrective action plan for alleged violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. In 2015, MHHS reported a patient to appropriate authorities for use of a fraudulent identification card. Although this was a permitted disclosure under HIPAA, MHHS impermissibly disclosed protected health information (PHI) by issuing press releases with the patient's name, disclosing PHI in meetings with the media and public officials, and in a statement on their website. The corrective action plan requires MHHS to update their policies and procedures and appropriately train their staff regarding disclosure of PHI. The takeaway for health care entities is that they may properly cooperate with law enforcement and disclose PHI, but in that process, they must be diligent to not disclose PHI in other impermissible ways.

C. HIPAA Breach Results In $400,000 Settlement

On April 7, 2017, Metro Community Provider Network (MCPN), a Colorado health center which annually serves 43,000 low-income individuals, agreed to a $400,000 HIPAA settlement and three-year corrective action plan with the Department of Health and Human Services Office for Civil Rights (OCR). The settlement resulted from a "phishing" incident involving employees' email accounts that enabled a hacker to obtain access to the electronic protected health information (ePHI) of 3,200 individuals.

The OCR found that MCPN took appropriate corrective action in reporting the incident. However, prior to the breach, MCPN failed to conduct the necessary risk assessments to detect the vulnerabilities in its ePHI environment. Therefore, MCPN had not implemented the necessary risk management plans to address risks and vulnerabilities in its system. In addition, when MCPN did finally conduct a risk analysis, it was insufficient to meet the requirements of the HIPAA Security Rule.

D. Medicaid Fraud Control Units Recovered Nearly $1.9 Billion in 2016

On May 19, 2017, the Department of Health and Human Services, Office of the Inspector General (OIG), published the Fiscal Year 2016 Report on Medicaid Fraud Control Units (Units), which investigate and prosecute Medicaid provider fraud and patient abuse or neglect. The Units

reported criminal and civil recoveries of nearly $1.9 billion while spending $259 million in State and Federal funds, for an average recovery of over $7 dollars for each dollar spent.

Unit investigations also resulted in 1,564 convictions. Fraud cases accounted for 74 percent of the convictions, while patient abuse or neglect accounted for the other 26 percent. Thirty-five percent of the convictions involved personal care services, such as home care aides and agency representatives. New Jersey reported 379 open fraud investigations, 21 fraud convictions, and 13 civil settlements for 2016. The total recovery in New Jersey was over $47.3 million. The full report can be found on the OIG's website: https://oig.hhs.gov/oei/reports/oei-09-17-00210.pdf

E. CHRONIC Care Act Passes Finance Committee Hurdle

On May 18, 2017, the Senate Finance Committee voted unanimously to approve the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act (S. 870). The Bill is intended to improve care management, coordination and outcomes for Medicare beneficiaries with chronic health conditions.

The Bill seeks to ensure these improvements by increasing access to telehealth for Medicare beneficiaries with chronic illnesses, including those in Medicare Advantage plans, as well as by providing more incentives for enrollees to receive care through accountable care organizations (ACOs). The Bill also seeks to extend a demonstration program, known as "Independence at Home," which aims to keep people in their homes rather than hospitals, allows reimbursement for more non-health and social services, and extends permanently "Medicare Advantage Special Needs Plans" that target chronically ill beneficiaries.

The Bill currently has 18 bipartisan cosponsors. Sen. Ron Wayden (D-Ore.), the Committee's ranking member, is confident the bill will move through the House given its support on both sides of the political aisle. Orrin Hatch (R-Utah), the Committee's chairman, praised the bipartisan teamwork involved in getting the bill through the committee, especially given the contentious nature of the current debate regarding healthcare.

F. CMS Updates Self-Referral Disclosure Protocol Form

The Centers for Medicare and Medicaid Services (CMS) recently issued a new form for reporting actual or potential violations of the Medicare physician self referral law under the Self-Referral Disclosure Protocol (SRDP). The SRDP was created to fulfill a requirement under the Patient Protection and Affordable Care Act to establish a self-referral disclosure protocol that sets forth a process to enable Medicare providers to self-disclose actual or potential violations of the physician self-referral statute.

The purpose of the new SRDP disclosure form is to create a streamlined and standardized format for disclosing actual and/or potential violations of the physician self-referral law, which will reduce the burden on providers and suppliers submitting disclosures to the SRDP and facilitate CMS' review of the self disclosures. Use of the new SRDP disclosure form is mandatory beginning June 1, 2017.

G. Office for Civil Rights Alerts to Threats to Security of HTTPS Transmissions

The US Department of Health and Human Services Office for Civil Rights (OCR) published a bulletin on April 3, 2017 warning of potential dangers using the security measure Secure Hypertext Transport Protocol (HTTPS) to transmit protected health information (PHI) and other confidential information over the Internet. Malicious attacks, called "man-in-the-middle" attacks, are specifically designed to intercept, read and/or modify these HTTPS communications. These attacks could result in the exposure of PHI, which would be a breach under the Health Insurance Portability and Accountability Act (HIPAA).

The United States Computer Emergency Readiness Team (US-CERT) has issued two alerts (TA15-120A and TA17-075A) with specific recommendations to improve the security of HTTPS communications. The OCR further recommends that health care organizations review the OCR's guidance on covered entities' obligations under HIPAA to render PHI "unusable, unreadable or indecipherable" through valid encryption processes.

H. OIG Releases Guide to Measure Compliance Program Effectiveness

On March 27, 2017, the Department of Health and Human Services, Office of Inspector General (OIG) published a resource guide for health care professionals to measure compliance program effectiveness entitled *Measuring Compliance Program Effectiveness: A Resource Guide*. The OIG worked closely with health care professionals in preparing the resource guide. The resource guide provides measurement options for a wide range of health care organizations, with diverse size, operational complexity, industry sectors, resources, and compliance programs. The guidelines focus on the following seven compliance program elements:

- Standards, Policies, and Procedures;
- Compliance Program Administration;
- Screening and Evaluation of Employees, Physicians, Vendors and other Agents;
- Communication, Education, and Training on Compliance Issues;
- Monitoring, Auditing, and Internal Reporting Systems;
- Discipline for Non-Compliance; and
- Investigations and Remedial Measures.

Within each of the elements is a list of compliance program metrics. The purpose of each metrics list is to give health care organizations as many ideas as possible regarding compliance program effectiveness, to be broad enough to help any type of organization, and to let each organization choose which metrics are best suited to its organizational needs. The lists are not intended to be used as a standard or for certification purposes. The resource guide can be found on the OIG's website located at: https://oig.hhs.gov/compliance/101/files/HCCA-OIG-Resource-Guide.pdf