BRACH | EICHLER LLC

Health Law UPDATE

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FEDERAL UPDATE

Increased FCA Settlements for Individual Providers Call for Renewed Focus on Corporate Compliance Plans

False Claims Act (FCA) settlements are increasingly requiring personal responsibility by individual health care providers.

In the fall of 2015, former Deputy Attorney General Sally Q. Yates issued guidelines, commonly referred to as the "Yates Memo," that called for Department of Justice (DOJ) fraud investigations to focus on individual accountability for corporate wrongdoing.

Since that time, DOJ investigations and settlements have increased the focus on liable individuals within corporations. Individual settlements have varied considerably with some as low as $10,000 and some as high as $20 million. For example, in a settlement finalized earlier this year, a pain management doctor was required to satisfy a multi-million-dollar judgment to the United States in part through the sale of several personal and commercial properties, gold bullion, sports memorabilia, boats, and jet skis. The doctor was accused of providing services that were not medically necessary and for using an unqualified medical assistant to perform intra-operative monitoring.

Health care providers should review their policies and procedures to minimize individual and corporate risk. In so doing, they should consider DOJ guidance on corporate compliance programs, which includes inquiry into:

- Whether there is an analysis of misconduct and remediation after misconduct is discovered
- Senior and middle management's commitment to promoting compliance, the compliance department's autonomy, experience, and resources
- The effectiveness of policies and procedures
- The effectiveness of the risk assessment process
- The effectiveness of employee compliance training and communication
- Whether there is an effective system for employees to report misconduct
- Whether there are policies to incentivize employee compliance and discipline employee compliance failures
- The type and frequency of internal audits, testing, and monitoring
- The procedures for ensuring due diligence and compliance integration in mergers and acquisitions.

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Administration Loosens ACA Rules and Halts Cost-Sharing Subsidies

On October 12, 2017, President Trump signed an executive order (EO) intending to loosen Affordable Care Act (ACA) insurance rules that would allow for the sale of cheaper policies with fewer benefits and consumer protections. A subsequent announcement was made halting the payment of the cost-sharing reductions (CSRs) to insurance companies.

The EO expands short-term plans such as association health plans, short-term limited duration insurance, and health reimbursement arrangements. Limited duration plans do not meet the ACA coverage mandates and, as such, are cheaper, have less benefits, and beneficiaries would be subject to the ACA penalty for not having insurance (although not currently being enforced).

The Trump administration argues that it cannot continue to make the CSR payments because only Congress has the constitutional power to make that expenditure. Trump's own comments cast doubt on this official stance, criticizing insurance companies for being subsidized by the ACA and adhering to the general Republican call to repeal the health care law. In response to the halting of the CSR payments, a bipartisan group of legislators have drafted legislation that would fund the CSRs for an additional two years. The health care community, including physician and hospital groups, has called for Congress to pass the legislation. In addition, 19 state attorneys general attempted to obtain a preliminary injunction to prevent the administration from halting the CSRs; on October 25, 2017, a California federal judge declined to grant the injunction.

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CMS Issues 2018 Home Health Payment Rule, Absent Controversial Home Health Groupings Model

Centers for Medicare & Medicaid Services (CMS) issued a final rule in the November 7, 2017 Federal Register, updating the calendar year (CY) 2018 Medicare payment rates and the wage index for Medicare home health agencies (HHAs). In so doing, CMS did *not* finalize the controversial and industry-debated Home Health Groupings Model (HHGM), stating in its November 1st announcement that "CMS is not finalizing the [HHGM] and will take additional time to further engage with stakeholders to move towards a system that shifts the focus from

volume of services to a more patient-centered model. CMS will take the comments submitted on the proposed rule into further consideration regarding patients' needs that strikes the right balance in putting patients first." *http://go.cms.gov/2mowRTw*

In addition to updating the CY 2018 Medicare payment rates and the wage index, the rule finalizes proposals for the Home Health Value-Based Purchasing (HHVBP) Model and the Home Health Quality Reporting Program (HH QRP). The final rule is effective January 1, 2018 and may be found at: *http://bit.ly/2jplTfG*

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Government Intervenes in Whistleblower Suit Against MRI Provider

The federal government has intervened in a whistleblower action under the federal False Claims Act (FCA) alleging a Delaware diagnostic testing company charged Medicare for magnetic resonance imaging (MRI) tests performed without necessary doctor supervision. *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 complaint alleges that Orthopaedic and Neuro Imaging LLC (ONI), a diagnostic imaging provider with several locations in Delaware and Maryland, and its owner, Richard Pfarr, administered contrast dye to patients without proper supervision from a physician. 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.

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. ONI is accused of billing Medicare for thousands of contrast dye injections performed without proper supervision, despite Pfarr signing an acknowledgement that he understood Medicare's requirements. In the case of one of its facilities, ONI allegedly made false submissions claiming that a physician in the same building as ONI's facility served as the supervising physician falsified an agreement between that physician and ONI regarding coverage by the physician, all without that physician's knowledge. Overall, ONI is alleged to have received reimbursement from Medicare in excess of $1.3 million related to false claims for contrast MRIs. The case serves as a reminder that providers must ensure appropriate supervision requirements are met under Medicare and other laws and rules.

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STATE UPDATE

NY Spine Group to Pay $1.9 Million for False Claims Investigation

A New York multi-location medical practice focusing on pain management and spine and back procedures has agreed to pay more than $1.9 million to the State of New York in repayment and fines to resolve claims by the New York U.S. Attorney's Office that it improperly billed Medicare for moderate sedation services.

In October 2011, the American Medical Association released guidance on the billing requirements for moderate sedation services to clarify that such services are billable only when the physician spends at least 16 minutes face-to-face with the patient. The Medicare Administrative Contractor for New York that processes providers' claims confirmed the 16-minute rule in February 2012 in an explanatory article released to its listserv, and also maintained on its website for a period of time.

During certain procedures, practice physicians placed patients under moderate sedation. Moderate sedation produces a state where the patient is sedated but retains the ability to respond to verbal direction and remains capable of maintaining the patient's airway without assistance.

The U.S. Attorney alleged the practice routinely billed for moderate sedation services when its physicians spent less than the required 16 minutes with the patient. These moderate sedation claims were submitted in connection with claims for underlying therapeutic and/or diagnostic services for which the practice also billed and was paid. This case serves as a reminder that pain management and other procedures requiring moderate sedation and other anesthesia services require careful timing, documentation, coding, and billing to ensure compliance with coding and billing rules.

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Hospital's Auto-Dialed Collection Calls Result in Lawsuit

Earlier this year, two plaintiffs filed suit against Rady Children's Hospital—San Diego alleging that they received autodialed calls from the hospital to their cell phones, in violation of the Telephone Consumer Protection Act (TCPA). *Crooks v. Rady Children's Hosp.,* No. 17CV246-WQH-MDD, 2017 WL 4541742 (S.D. Cal. Oct. 10, 2017).

The two plaintiffs sent cease and desist letters to the hospital after receiving multiple phone calls. They allege the hospital continued to call via an automatic telephone dialing system and prerecorded message seeking outstanding debts owed. Further, the plaintiffs alleged they incurred charges relating to the autodialed calls.

The TCPA, in short summary, protects consumers from certain types of autodialed calls that are not of an emergent nature and that have not been expressly consented to. In July 2015, the Federal Communications Commission (FCC) issued an order that provided for exemptions to the TCPA, allowing for certain autodialed calls and prerecorded health care messages without the prior express consent of consumers, provided the consumers are not charged for the calls and the calls are not counted against consumers' plan limits. These include calls regarding appointments and exams, confirmations and reminders, wellness checkups, hospital pre-registration instructions, pre-operative instructions, lab results, post-discharge follow-up intended to prevent readmission, prescription notifications, and home healthcare instructions.

The hospital urged the court to stay the case pending the outcome of another case, *ACA International v. FCC*, No. 15-1211 (D.C. Cir. filed Nov. 25, 2015), which focused on the definition of "autodialers." The hospital argued it would suffer unnecessary discovery if the case moved forward before a decision in the *ACA International v. FCC* case.

On October 11, 2017, the court rejected the hospital's argument and, as a result, the lawsuit will move forward.

The case should serve as a reminder and warning for health care providers to ensure they understand permissible and impermissible

practices under the TCPA and other laws, including privacy laws, prior to establishing autodial or other automated systems for contacting patients.

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Florida Supreme Court Rules in Favor of Patient Access to Adverse Medical Incident Reports

On October 26, 2017, the Florida Supreme Court, in a split decision, ruled that a 2004 amendment to the Florida Constitution (Amendment 7) provides patients with substantial rights to access adverse incident review reports produced by medical providers in preparation for medical malpractice actions. *Amber Edwards v. Larry D. Tomas, M.D., et al.* (SC15-1893). Amendment 7, also known as the "Patients' Right to Know About Adverse Medical Incidents" amendment, provides, in part, that patients have a right to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident.

The plaintiff had initially brought a medical malpractice action against a hospital and her physician for allegedly severing her common bile duct during gallbladder removal surgery. The Florida Circuit Court ordered production of external peer review reports concerning medical care and treatment rendered by the physician under Amendment 7, preempting statutory discovery protections for records regarding adverse medical incidents. The hospital petitioned for *certiorari* review. The Florida District Court of Appeal granted the petition and quashed the order in part. The plaintiff then petitioned for review by the Florida Supreme Court, which was granted.

The Florida Supreme Court held the following: (1) the constitutional right granted by Amendment 7 to any adverse medical incident reports in medical malpractice actions removed all limitations on discovery of adverse medical incidents; (2) the external peer review reports were adverse medical incident reports; (3) the external peer review reports were made or received in the course of business, and therefore were discoverable in the medical malpractice action pursuant to Amendment 7; (4) the external peer review reports did not contain opinions of counsel, and therefore discovery of the reports was not precluded by work product privilege in the medical malpractice action; and (5) the external peer review reports did not contain communications between counsel and client, and therefore discovery of the reports was not precluded by attorney-client privilege in the medical malpractice action.

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New Jersey Legislative Update

Minimum Medicaid Reimbursement Rate for Personal Care Services—On October 6, 2017, Assembly Bill 320 was signed into law, mandating a minimum reimbursement rate of $15.50 per hour for Medicaid personal care services. The minimum rate applies whether the services are provided in the Medicaid fee-for-service delivery system or through a managed care delivery system. The reimbursement rate for personal care services in the Medicaid fee-for-service program has been $15.50 for several years. However, the shift of most Medicaid personal care services to a managed care delivery system has allowed private managed care organizations to unilaterally reduce reimbursement rates to already struggling provider agencies and health care workers.

Access to Prescription Monitoring Information Without Requirement for Court Order or Subpoena—On October 5, 2017, S3426 was introduced in the New Jersey Senate to allow state, federal, and municipal law enforcement officers access to prescription monitoring information without the need for a court order or subpoena, as is required under current law. The officer will be required to certify that the officer is engaged in a bona fide specific investigation of a designated practitioner, pharmacist, or patient. A5172 had previously been introduced in the New Jersey Assembly on August 24, 2017.

Notice of Cancellation of Certificate of Need Call for Burn Center Programs or Units—On October 2, 2017, the Department of Health published a notice that the April 1, 2016 call for certificate of need applications for burn center programs or units is cancelled. The Department reviewed utilization data and determined that there is not a sufficient need for additional burn center programs or units at the present time.

Notice of Certificate of Need Call for New Pediatric Intensive Care Beds—The Department of Health is inviting certificate of need applications on an expedited review basis to establish new pediatric intensive care beds. The Department determined that, based on an analysis of utilization data for 2014, 2015, and 2016 and in acknowledgement that pediatric intensive care units are relatively small, there is a need for an increase in the number of beds required to ensure proper access during periods of increased need. The call is limited to those providers who are currently licensed to provide pediatric intensive care services in Essex, Middlesex, Monmouth, Morris, and Passaic counties.

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Brach Eichler In The News

Brach Eichler is representing two plaintiffs in a suit against insurer Aetna for, among other things, breach of privacy relating to Aetna's mailing of notices to beneficiaries regarding HIV medications. For more information: *http://bit.ly/2mpNApJ* or contact **Lani M. Dornfeld.**

John D. Fanburg is presenting a legal report at the 67th Annual Slide Seminar and Annual Meeting of the New Jersey Society of Pathologists. For more information: *http://bit.ly/2jqfwbK*

HIPAA CORNER

OCR Issues Guidance in Response to Trump's Declaration of Opioid National Public Health Emergency

Just one day after President Trump declared a nationwide public health emergency regarding the opioid crisis, on October 27, 2017, the Department of Health and Human Services, Office for Civil Rights (OCR) issued guidance entitled "How HIPAA Allows Doctors to Respond to the Opioid Crisis." The guidance document may be found at: *http://bit.ly/2hzmCKG*. The document discusses how and when providers may share health information with the patient's family, friends, and others when the patient may be in a crisis and incapacitated, such as during an opioid overdose.

The guidance summarizes when providers may share some health information with the patient's family and others during certain crisis situations, without obtaining the patient's specific authorization, including:

- Sharing health information with family and close friends involved in the patient's care if the provider determines such sharing is in the best interests of an incapacitated or unconscious patient and the information shared is directly related to the family or friend's involvement in the patient's care or payment for the patient's care. In this circumstance, the provider:
  - May: Using the provider's professional judgment, talk with the parents of a patient incapacitated from an opioid overdose, with the discussion limited to the overdose and related medical information.
  - May Not: Share medical information unrelated to the overdose, unless written authorization is obtained from the patient after capacity is regained.
- Informing persons in a position to prevent or lessen a serious and imminent threat to a patient's health or safety. In this circumstance, the provider:
  - May: Inform family, friends, or caregivers of the patient's opioid abuse, if upon discharge after an opioid overdose the provider determines that the patient poses a serious and imminent threat to his or her health through continued opioid use.

As to the patient's decision-making capacity, the OCR reminded providers that:

- If an adult patient has decision-making capacity and there is currently no serious and imminent threat of harm, the provider must give the patient the opportunity to agree or object before sharing the patient's health information with family, friends, and others involved in the patient's care or payment for the patient's care. If the patient objects, the information may not be shared.
- Because incapacity may be temporary and situational, if a patient regains capacity at any time, the provider must at that time give the patient the opportunity to agree or object before sharing the patient's health information with family, friends, and others involved in the patient's care or payment for care. In this regard, the OCR offered the following example:

  "[A] patient who arrives at an emergency room severely intoxicated or unconscious will be unable to meaningfully agree or object to information-sharing upon admission but may have sufficient capacity several hours later. Nurses and doctors may decide whether sharing information is in the patient's best interest, and how much and what type of health information is appropriate to share with the patient's family or close personal friends, while the patient is incapacitated and so long as the information shared is related to the person's involvement with the patient's health care or payment for such care. If the patient's capacity returns and the patient objects to future information sharing, the provider may still share information to prevent or lessen a serious and imminent threat to health or safety as described above [in the guidance document and briefly summarized above in this article]."

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