BRACH | EICHLER LLC

Healthcare Law UPDATE

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FEDERAL UPDATE

Federal Law Expands on Scope of Practice for PAs in the Hospice Setting

On November 15, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a Final Rule, effective January 1, 2020. This new federal law expands the scope of practice for physician assistants (PAs) in the hospice setting. It permits such mid-level, nonphysician practitioners to order drugs for hospice patients, which was an act previously reserved only for physicians and nurse practitioners (NPs).

This new authority is limited to drug orders generated outside the hospice's operations. The PAs who are placing drug orders for hospice patients also may not be employed by or contract with the hospice, and the PA must be the patient's attending physician. Further, PAs will still be subject to the applicable state's scope of practice requirements and other hospice policies as the states may enact. CMS hopes that by expanding the scope of authority for PAs in the hospice setting under the federal rules, there will be greater care coordination for hospice patients.

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DOJ Alleges Medicare Was Fraudulently Billed $2.1 Billion for Genetic Cancer Testing

Pursuant to a press release issued by the federal Department of Justice (DOJ), 35 defendants were charged with fraudulently billing Medicare more than $2.1 billion for genetic cancer testing. The investigation addressed criminal acts involving "payment of illegal kickbacks and bribes by cancer genetic testing laboratories in exchange for the referral of Medicare beneficiaries by medical professionals working with fraudulent telemedicine companies for expensive cancer genetic tests that were medically unnecessary." Some of the defendants allegedly orchestrated a telemarketing network that victimized elderly and/or disabled patients nationwide. The defendants allegedly paid medical professionals to prescribe cancer genetic testing to patients they did not interact with or only briefly interacted with on the phone.

Deputy Inspector General for Investigations, Gary L. Cantrell of HHS-OIG, stated, "Unfortunately, audacious schemes such as those alleged in the indictments are pervasive and exploit the promise of new medical technologies such as genetic testing and telemedicine for financial gain, not patient care. Instead of receiving quality care, Medicare beneficiaries may be victimized in the form of scare tactics, identity theft, and in some cases, left to pay out of pocket." In order to prevent additional financial losses, CMS Administrator Seema Verma states, "CMS continues to use a comprehensive and aggressive program integrity approach that includes fraud prevention, claims review, beneficiary education, and targeting high-risk areas of the federal healthcare programs with new tools and innovative demonstrations."

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Medicare Overpayments to Acute-Care Hospitals

The U.S. Department of Health & Human Services, Office of Inspector General (OIG) released a report dated November 2019 (the "November 2019 Report"), which provided its findings showing that Medicare improperly paid $54.4 million for 18,647 claims subject to Medicare's post-acute-care transfer policy (Transfer Policy). Prior to issuing the November 2019 Report, the OIG conducted audits and found that Medicare improperly paid claims related under the Transfer Policy for nearly $242 million. The November 2019 Report was commissioned to determine if the previous recommendations by the OIG were adhered to and if such recommendations and their implementation helped lower the number of overpayments by Medicare. The OIG found in earlier audits that some Medicare contractors claimed they had not received the automatic notifications of improperly billed claims nor did they take action on those claims to adjust them.

The November 2019 Report was based on claims which had dates of service from January 1, 2016 through December 31, 2018. The overpayments by Medicare are a result of the improper use of patient discharge status codes when completing claims subject to the Transfer Policy. Medicare pays an acute-care hospital that transfers a patient to post-acute care a per diem rate for each day of the patient's stay in the

hospital. Medicare makes the full Medicare Severity Diagnosis-Related Group ("MS-DRG") payment to an acute-care hospital that discharges an inpatient to his/her home or certain types of healthcare institutions, for instance certain institutions providing custodial care. The OIG found that none of the 18,647 claims should have been reimbursed for the full MS-DRG payment. Rather, these claims should have been reimbursed at the per diem rate when the patient was discharged and then receiving either home health services or other post-acute care at another facility, such as a skilled nursing facility.

The overpayment of $54.4 million represents the difference between the full MS-DRG payment and the amount that should have been paid at the per diem rate. As a result of the OIG's findings, the OIG recommended that CMS direct the Medicare contractors to: "(1) recover the $54.4 million in identified overpayments, (2) identify any claims for transfers to post-acute care in which incorrect patient discharge status codes were used and direct the Medicare contractors to recover any overpayments after our audit period, and (3) ensure that the Medicare contractors are receiving the postpayment edit's automatic notifications of improperly billed claims and are taking action by adjusting the original inpatient claims to initiate recovery of the overpayments."

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CMS Issues New Price Transparency Rules For Hospitals and Health Plans

On November 15, 2019, the Centers for Medicare & Medicaid Services (CMS) issued two rules advancing the Trump administration's goals of improving price and quality transparency in healthcare.

The first is a final rule implementing Section 2718(e) of the Public Health Service Act requiring each hospital operating in the United States to establish, update, and make public an annual list of the hospitals' standard charges for items and services provided by the hospital, including for diagnosis-related groups. The rule, which would be effective January 1, 2021, finalizes: the definitions of "hospital," "standard charges," and "items and services;" the requirements for making public a machine-readable file online that includes all standard charges for all hospital items and services; the requirements for making public prices for discounted cash payments, payer-specific negotiated charges, and the lowest and highest charges negotiated with all third-party payors for at least 300 "shoppable services" that are presented in a consumer-friendly manner; and the monitoring and action requirements for hospital noncompliance, including audits, corrective action plans, and penalties of $300 per day, as well as a process for hospitals to appeal these penalties.

The second rule is a proposed Transparency in Coverage rule which would require most group health plans, including self-insured plans, and health insurance issuers in the individual and group markets to disclose price and cost-sharing information to participants, beneficiaries, and enrollees. The proposed rule would not apply to grandfathered health plans that existed prior to the Affordable Care Act. The rule would give healthcare consumers real-time, personalized access to estimates of their cost-sharing liability for all covered health care items and services. The information would be provided through an online tool, and in paper form upon request, that group health plans and issuers must make available to all of their members. The goal is to enable healthcare consumers to shop and compare costs between specific providers prior to receiving care. The plans and issuers would also be required to disclose on a public website their negotiated rates for in-network providers and the allowed amounts paid for out-of-network providers. Written comments to the proposed rule may be submitted to CMS for 60 days from the release of the rule. The rule would take effect for plan or policy years beginning one year after the finalization of the rule.

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STATE UPDATE

New Jersey Board of Dentistry Proposes Significant Changes to Regulations

On November 18, 2019, the New Jersey Board of Dentistry (BOD) released numerous amendments, repeals and new rules in order to implement new statutes; update rules, terminology, citations, website addresses, and names of licensure examinations; and clarify and codify current standards of practice and licensure and registration requirements. Many of the proposed changes are intended to enhance the safety of patients as well as dental professionals.

The BOD noted that due to adverse incident reports from across the country concerning deeper levels of sedation in patients than intended, amendments to sedation rules, in particular, are needed. In this regard, the BOD-proposed rules would require training and certification in both basic life support and advanced cardiac life support for licensed dentists and for employed staff (at least one to assist and one present in the office) whenever parenteral conscious (moderate) sedation, enteral sedation or general anesthesia is used. The rules would further require that the facility in which the anesthesia is administered contain an emergency drug kit, including analgesics, local anesthetics, vasopressors, vasodilators, and many other drugs, as well as emergency equipment, including battery-powered clocks or watches, suction equipment, respiration monitoring equipment, and many other items. The rules would also require the facility's physical space for the operating and recovery areas to meet size and lighting requirements. Dentists engaging in these forms of anesthesia would also be required to maintain contemporaneous anesthetic records. Lastly, the rules would increase the

required training and competencies for licensees administering parenteral conscious sedation, particularly in the management of complications, interactions, and medical emergencies.

The BOD has also proposed certain mandatory continuing education courses for each biennial license registration period, including cardiopulmonary resuscitation, infection control, professional ethics, and New Jersey law concerning the practice of dentistry, and opioids. To incentivize charity care, a proposed rule would permit licensees to request a waiver of half of the required continuing education hours (outside of the mandatory courses) if the licensee provides volunteer dental services.

Comments to the proposed amendments, repeals, and new rules may be submitted to the BOD until January 17, 2020.

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New Jersey Legislative Update

Proposed Bill to Authorize Dispensing Medical Marijuana Through Telemedicine – On November 7, 2019, Bill S4171 was introduced in the New Jersey Senate to permit dispensing medical marijuana through telemedicine and telehealth under certain circumstances. An identical bill was introduced in the New Jersey Assembly on November 25, 2019. Under the Bill, for 270 days following the date of the Bill's enactment, a healthcare practitioner may authorize a patient who is a child, resident of a long-term care facility, developmentally disabled, terminally ill, receiving hospice care, or housebound as certified by the patient's physician, for the medical use of cannabis using telemedicine and telehealth. Thereafter, a healthcare practitioner may authorize any patient for the medical use of cannabis using telemedicine and telehealth, provided that, and except in the case of a patient who is a child, developmentally disabled, terminally ill, receiving hospice care, or housebound, the patient has had at least one previous in-office visit with the practitioner prior to the patient's authorization for the medical use of cannabis.

Proposed Bill to Require Health Insurance Coverage for Mental Health Screening – On November 25, 2019, Bill A5989 was introduced in the New Jersey Assembly to require health insurance coverage for annual mental health screenings. The Bill would be applicable to health, hospital, and medical service corporations; commercial individual and group health insurers; health maintenance organizations; health benefits plans issued pursuant to the New Jersey Individual Health Coverage and Small Employer Health Benefits Programs; and the State Health Benefits Program.

Bill to Require Licensure of Embryo Storage Facilities Passes New Jersey – On December 4, 2019, Bill S3075 was signed into law by Governor Phil Murphy to regulate and license embryo storage facilities. The Bill provides that a person cannot conduct, maintain, or operate an embryo storage facility in New Jersey unless licensed by the Department of Health (DOH). The DOH must now promulgate regulations to govern the storage and care of human eggs, pre-embryos, and embryos by an embryo storage facility in accordance with Standards ISO 9001 and ISO 20387 of the International Organization for Standardization; standards for biorepositories established by the College of American Pathologists Biorepository Accreditation Program; and the U.S. Food and Drug Administration guidance on Current Good Tissue Practices.

Amendments to Regulations Governing Supervision of Certified Alcohol and Drug Counselors – On December 2, 2019, the New Jersey State Board of Marriage and Family Therapy Examiners adopted amendments to the regulations governing the supervision of Certified Alcohol and Drug Counselors. Under the amendments, a New Jersey licensed clinical alcohol and drug counselor may now serve as a qualified clinical supervisor of certified alcohol and drug counselors and interns, if (i) he or she is also a New Jersey certified advanced practice nurse, licensed psychologist, licensed clinical social worker, licensed marriage and family therapist, or licensed professional counselor, (ii) is deemed a qualified supervisor by the other respective professional licensing board, and (iii) has three years of clinical experience in alcohol and drug counseling. The Board determined that it is not necessary to require these dually licensed mental health professionals to hold the "Certified Clinical Supervisor" certification which other qualified supervisors are required to hold because combining the education and experience of a clinical alcohol and drug counselor with the supervision, training, or experiential requirements of the other professional license will ensure the quality and competency of the supervision provided by these individuals.

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Brach Eichler In The News

Managing Member and Healthcare Law Chair **John D. Fanburg** and Litigation Member **Charles X. Gormally** recently released Brach Eichler's Third Cannabis White Paper, "New Jersey Cannabis: Observations on Opportunity Lost Along the Way."

On December 4, **John D. Fanburg** moderated a panel at the Withum Healthcare Symposium, "Healthcare in New Jersey—Affiliations, Mergers, Private Equity, and Physician Alignment."

John D. Fanburg addressed "What Every Pathologist Should Know About Telemedicine" at the annual meeting of the New Jersey Society of Pathologists on 11/23.

The results of The Brach Eichler 2019 New Jersey Healthcare Monitor, a survey of New Jersey healthcare practitioners, were released on December 18. NJ101.5.com wrote about the findings, as did *ROI-NJ*. Healthcare Member **Joseph M. Gorrell**, as well as **John D. Fanburg**, was quoted.

HIPAA CORNER

OCR Secures Almost $2.2 Million HIPAA Settlement – On November 27, 2019, the U.S. Department of Health & Human Services (HHS) issued a press release reporting that Sentara Hospitals (Sentara) entered into an agreement with the Office for Civil Rights (OCR) in which it agreed to pay $2.175 million to settle potential violations of the HIPAA Breach Notification and Privacy Rules, and agreed to a robust corrective action plan. The agreement settled allegations relating to complaints of medical bills of patients sent to wrong individuals, and the failure of Sentara to timely and properly report the breach incidents to the affected individuals and the OCR. The settlement highlights two important HIPAA requirements. The first is the obligation for covered entities to thoroughly investigate each suspected or actual breach of PHI, and to perform a proper risk assessment to determine whether or not the incident is a "reportable" breach. Notification of reportable breaches must be sent to affected individuals within 60 days. Some breaches must be reported to the media, and all breaches must be reported to the OCR (the timing of OCR notification will depend on size of breach). The second requirement addressed in this settlement is the requirement for each covered entity to have a business associate agreement in place with each and every business associate providing services to the covered entity. In other OCR settlements, we have seen a penalty as high as $500,000 for the failure to do so.

Fall OCR Cybersecurity Newsletter – On December 2, 2019, the OCR published its Fall 2019 OCR Cybersecurity Newsletter, *What Happened to my Data?: Update on Preventing, Mitigating and Responding to Ransomware*. The newsletter provides information on the evolution of ransomware attacks, prevention, mitigation, and recovery, and whether or not to pay the ransom demand.

OCR Settles Second Right of Access Initiative Case – On December 12, 2019, the OCR announced its second enforcement action and settlement under OCR's "HIPAA Right of Access Initiative." OCR announced the initiative earlier this year, "promising to vigorously enforce the rights of patients to get access to their medical records promptly, without being overcharged, and in the readily producible format of their choice." This $85,000 settlement with a Florida-based primary care and interventional pain management provider resulted from allegations that the provider failed to timely provide medical records to a third party as requested by the patient after receiving the request for the records, failed to provide the records in the electronic format requested by the patient, and charged more than the reasonable cost-based fee permitted under HIPAA.

Interplay Between HIPAA and FERPA – The HHS OCR and Department of Education released updated joint guidance on December 19, 2019 addressing the application of the federal Family Educational Rights and Privacy Act (FERPA) and HIPAA to records maintained on students. In particular, the guidance clarifies for school administrators, healthcare professionals, families, and others how FERPA and HIPAA apply to education and health records maintained about students.

If you would like assistance with your HIPAA privacy and security program, in managing a breach incident or in business associate analysis and contracting, contact:

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