BRACH | EICHLER LLC

Health Law UPDATE

October 2018

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FEDERAL UPDATE

President Trump Signs Bipartisan Opioid Legislation into Law

On October 24, 2018, President Trump signed into law the Patients and Communities Act. This bipartisan legislation addresses various issues related to the opioid crisis, which President Trump has declared a national emergency. The opioid crisis has a far-reaching impact on communities throughout the United States. According to the CDC, on average, 115 Americans die every day from an opioid overdose. Consequently, the law provides for the National Institutes of Health to conduct research such as finding a new non-addictive painkiller. Additionally, the law addresses treatment and recovery and substance abuse prevention. For example, the law contains new programs for the health care workforce such as increases in education and training in pain care. Updates to pain care programs under the law include alternatives to opioid pain treatment and promotion of non-opioid plan treatments. The new law also contains provisions to assist law enforcement and allows non-profit organizations to provide training and technical assistance to drug courts.

Though the new law represents significant progress in combating the opioid epidemic, others warn that it cannot be seen as the final solution. Former Democratic congressman and mental health advocate Patrick Kennedy stated, "I hope Congress doesn't think they can put this behind them because they passed these bills. It takes an urgency like we had during HIV-AIDS. That will call to mind what it takes to address a crisis, it takes political will." Associate Director of Health Law and Policy at Center on Addiction, Lindsey Vuolo, also warns there is more to be done. Ms. Vuolo stated, "This legislation edges us closer to treating addiction as the devastating disease it is, but it neglects to provide the long-term investment we've seen in response to other major public health crises."

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U.S. Surgeon General Issues Report on Opioid Addiction in America

On September 19, 2018, the U.S. Surgeon General, Dr. Jerome Adams, along with the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA), issued a report entitled, "Facing Addiction in America: The Surgeon General's Spotlight on Opioids." In the preface to the Report, Dr. Adams explained that his younger brother has struggled with substance abuse disorder, which started with untreated depression leading to opioid misuse and eventual incarceration. Noting that his family's experience is not uncommon for many Americans, Dr. Adams urges readers to understand that "opioid use disorder is a chronic but treatable brain disease, and not a moral failing or character flaw... [t]he way we as a society view and address opioid use disorder must change—individual lives and the health of our nation depend on it."

In the Report, Dr. Adams offered the following recommendations for health care professionals and associations to help combat and prevent opioid misuse:

- Address substance-use-related health issues with the same sensitivity and care as any other chronic health condition
- Support high-quality care for substance use disorders
- Follow the gold standard for opioid addiction treatment
- Follow the CDC Guideline for Prescribing Opioids for Chronic Pain
- When opioids are prescribed, providers can assess for behavioral risk factors to help inform treatment decisions
- Refer patients to opioid treatment providers when necessary
- Become qualified to prescribe buprenorphine for the treatment of opioid use disorder

The Report also details that in 2017, an estimated 11.1 million people aged 12 and older had misused prescription pain relievers. Additionally, the Centers for Disease Control and Prevention (CDC) estimated that 47,872 people died from an opioid overdose in 2017—a figure which amounts to more than 131 deaths per day on average. What's even more worrying, however, are the three trends driving what the Report calls the "opioid crisis": (1) a five-fold increase in opioid overdose deaths since 1999; (2) a four-fold increase in heroin overdoses since 2010; and (3) the tripling death rate for synthetic opioids such as the high-powered drug, fentanyl, since 2013. However, despite these staggering statistics, only 53% of Americans consider opioid addiction to be a pressing concern, according to the Report.

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OIG Report on FDA Cybersecurity Review

The Department of Health & Human Services (DHHS) Office of Inspector General (OIG) released a report in September 2018 finding that the Food and Drug Administration (FDA) should do more to integrate cybersecurity concerns in its premarket review process for medical devices. Networked medical devices, such as infusion pumps,

diagnostic imaging equipment, and pacemakers, are increasingly used to deliver care, remotely monitor patients, and transfer patient data. Without appropriate security controls, these devices can be vulnerable to cybersecurity threats. For example, an unauthorized user could remotely control a networked infusion pump and maliciously change the medication dosage delivered to a patient, as the FDA warned in 2015.

In October 2014, FDA issued a guidance document, "Content of Premarket Submission for Management of Cybersecurity in Medical Devices," to assist manufacturers in preparing their premarket submissions for networked medical devices and to guide FDA during its review. The OIG report found, however, that despite the 2014 guidance, FDA often needs to request supplemental cybersecurity information from manufacturers during the premarket review process, creating significant inefficiencies.

OIG now recommends that FDA take the following additional steps to more fully integrate cybersecurity in its premarket review process: (1) promote the use of pre-submission meetings to address cybersecurity-related questions; (2) include cybersecurity documentation as a criterion in FDA's "Refuse-To-Accept" checklists which the agency uses to screen submissions for completeness; and (3) include cybersecurity as an element in its Smart template, the guide it uses to review submissions. FDA concurred with all three recommendations. FDA may now consider cybersecurity risks and controls in its overall assessment of the safety and effectiveness of a device.

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CMS Proposes New Revisions to Regulations Aimed at Streamlining and Clarifying Medicare Coverage Determination Appeals Procedures

On October 2, 2018, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule in the Federal Register aimed at revising the current Medicare Part A, Part B, and Part D regulations setting forth the appeals process for beneficiaries, providers, and suppliers seeking to appeal adverse benefit or coverage determinations. In the proposed rule, CMS stated that "these changes would help streamline the appeals process and reduce administrative burden on providers, suppliers, beneficiaries, and appeal adjudicators. These revisions, which include technical corrections, would also help to ensure the regulations are clearly arranged and written to give stakeholders a better understanding of the appeals process." Moreover, CMS's aim in proposing these changes is to promote consistency between various statutes and regulations, and to reduce confusion of relevant stakeholders.

Some of the proposed changes and revisions to the Medicare coverage and benefit determination appeals regulations include, but are not limited to:

- Removing the requirement that appellants must sign appeal requests
- Changing the timeframe for vacating dismissal of an appeal request of a coverage determination from six months to 180 days from the date of the notice of dismissal
- Correcting regulations to remove references to SSN-based Health Insurance Claim Numbers (HICNs) and replacing HICNs with language pertaining to the new randomly generated Medicare Beneficiary Identifier (MBI) numbers to comport with Section 501 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)
- Removing provisions deemed redundant by CMS at 42 C.F.R. §§ 423.1970, 423.1972, 423.1974, and 423.1976, while combining appropriate provisions contained therein with other sections of the Medicare regulations, including 42 C.F.R. §§ 423.2006, et seq.
- Changing the timeframe for CMS and its contractors to refer decisions or dismissals by the Office of Medicare Hearings and Appeals (OHMA) to the Medicare Appeals Council (the "Council") from 60 days after the date the decision or dismissal from the OHMA is issued to five calendar days after the decision or dismissal is received by CMS or its contractors
- Establishing a number of other technical changes CMS deems to be necessary in effectively implementing the provisions of its January 17, 2017 Final Rule, providing other changes to regulations also designed to streamline Medicare appeals procedures, among other things.

Interestingly, CMS estimates that the proposed rule, if finalized, would result in an annual savings to Medicare of nearly $11.8 million per year. That said, the proposed rule must first pass through notice-and-comment rulemaking, and CMS seeks comments to the proposed rule from relevant stakeholders no later than 5:00 p.m. on December 3, 2018.

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CMS Considering Sanction Rules for Nursing Home Staff

Centers for Medicare & Medicaid Services (CMS) is considering a proposed rule that would permit enforcement actions against nursing home staff in cases of elder abuse or other illegal activities. According to the FY2019 Mission & Priority Document published by CMS this month, which provides an overview of CMS's current activities and priorities for the coming year, the proposed regulation would allow CMS to impose civil money penalties, or CMPs, of up to $200,000 against nursing home staff or volunteers who fail to report reasonable suspicion of certain crimes committed in long-term care facilities. In addition, the proposed regulation would allow a two-year exclusion from federal health programs for retaliating against individuals who report crimes.

The new regulation would implement Section 1150B of the Social Security Act, which was adopted in 2010 as part of the Affordable Care Act. Section 1150B requires certain "covered individuals," including each individual who is an owner, operator, employee, manager, agent, or contractor of a long-term care facility that receives at least $10,000 in certain federal funds during the preceding year, must report to CMS and local law enforcement any reasonable suspicion of a crime (as defined by the law of the applicable political subdivision) against any individual who is a resident of, or is receiving care from, the facility. While CMS has the authority to impose fines against nursing homes, a new rule is required to impose sanctions against staff or volunteers of these facilities. The announcement comes a year after the Office of Inspector General released a report criticizing CMS for not doing enough to ensure that cases of potential abuse or neglect get reported.

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Oral Implant Groups Bring Monopoly Suit Regarding Specialty Certification

On September 25, 2018, the United States Board of Oral Implantology (USBOI) and the International Congress of Oral Implantologists (ICOI) sued the American Board of Dental Specialties (ABDS), the American Board of Oral Implantology (ABOI), the American Academy of Implant Dentistry (AAID) and others alleging a scheme to monopolize the implantology specialist certification markets.

In the suit, the USBOI and the ICOI claim that the defendants seek to enrich themselves by maintaining a monopoly in specialist certifications in the field of oral implantology, thus "foreclosing competition and permitting defendants to set prices for a range of required services, courses, memberships, and professional materials above competitive levels." The plaintiffs allege in the complaint that the defendants "engaged in a multi-year, deceptive scheme—effected through litigation; false and misleading statements to government officials, the dental community, and the public; and the creation of a front organization that cynically held itself out as a neutral, objective arbiter—to ensure that only members of the AAID and ABOI could receive the coveted (and financially valuable) specialist certification."

The complaint brings claims for conspiracy to violate anti-trust laws, monopolization, and deceptive trade practices.

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STATE UPDATE

New Jersey Legislative Update

Bill Introduced Regarding Ultrasounds on Pregnant Women—On September 13, 2018, Bill (A4399) was introduced in the New Jersey Assembly requiring certain ultrasounds on pregnant women to be performed by licensed health care professionals. An identical bill was introduced in the New Jersey Senate on September 24, 2018. The Bill provides that the performance of any ultrasound on a pregnant woman in a limited service pregnancy center must be performed by a health care professional whose scope of practice includes performing ultrasounds. A limited service pregnancy center is an organization, including a pregnancy counseling organization or crisis pregnancy center, that for a fee or free of charge provides pregnancy counseling or information but does not perform abortions or make referrals to an abortion provider and is not licensed or certified by the State of New Jersey or the federal government to provide medical or health care services.

Bill to Regulate Drug Prices Reported Favorably in Senate—On September 24, 2018, the Senate Health, Human Services and Senior Citizens Committee reported favorably on Bill S977, which prohibits any person from charging excessive prices for drugs developed by publicly funded research. Under the Bill, if a drug, biologic, or other health care technology approved by the federal Food and Drug Administration was developed, partially or entirely, through research and development that is directly or indirectly supported by the federal or New Jersey State government, it is unlawful for any person to sell, offer to sell, or advertise for sale the drug, biologic, or technology to any purchaser in New Jersey at a unit price that is greater than a benchmark unit price or that constitutes discriminatory pricing. The benchmark unit price for a drug, biologic, or other health care technology is the lowest price charged to countries in the Organization for Economic Co-Operation and Development for the same drug, biologic, or technology, that have the largest gross domestic product with a per capita income that is not less than half of the per capita income of the United States.

Law Amending Out-of-State Professional Licensing Reciprocity Enacted—On August 10, 2018, Bill A1531 was signed into law by Governor Phil Murphy to revise the laws concerning reciprocity for out-of-State professionals and occupational licenses. The new law revises the law created to provide a streamlined reciprocity process for out-of-State professional and occupational licensing, with specific regard to jurisdictions with "substantially equivalent" standards to that of New Jersey. The new law provides that a person seeking reciprocity in New Jersey, who is required by law to provide documentation proving that their out-of-State license is valid, current, and in good standing in the other state, will have six months, following the date that a natural disaster or other catastrophic event occurs in the other state, to submit the documentation to a professional or occupational licensing board in New Jersey. The six-month grace period provided by the new law only would apply if the professional or occupational licensing board, upon inquiry, determines that the issuing state is unable to provide the documentation in a timely manner following the natural disaster or catastrophic event. In such a case, the person must submit the required documentation as soon as practicable.

Opioid Education Rules Proposed for Optometrists—On October 1, 2018, the New Jersey State Board of Optometrists proposed amending the continuing education requirements for optometrists to include education on the prescription of hydrocodone and opioids in accordance with New Jersey law. Specifically, one of the 50 credits of continuing education required of an optometrist with an active registration renewal would need to be on hydrocodone or opioids in general. The one-credit requirement would be incorporated into the 30 credits required on therapeutic pharmaceutical agents. The Board is also proposing a rule to allow a registrant to seek a waiver of the one-credit requirement. Written comments on these proposals are due by November 30, 2018.

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Brach Eichler In The News

John D. Fanburg commented in *Forbes* about the growth of the marijuana industry in New Jersey on September 24.

John D. Fanburg and **Jonathan J. Walzman** authored a three-part series on telemedicine in *Medical Economics* that appeared throughout September 2018.

Mark Manigan was named to *ROI-NJ*'s first-ever Health Care Influencers List on October 8.

Lani M. Dornfeld will speak on November 7 at a webinar titled, "Revisions to Medicare Home Health Moratoria Access Waiver Demonstration," hosted by the Home Care Association of Florida.

To view a full listing of recent news items and to read the articles mentioned above, please visit *http://bit.ly/2tYYFba*.

HIPAA CORNER

Anthem Settles with OCR for Record-Breaking $16M in "Largest U.S. Health Data Breach in History"

The Department of Health & Human Services, Office for Civil Rights (OCR) announced this month that health insurer Anthem, Inc. has agreed to pay $16 million to OCR and take "substantial corrective action" to settle potential HIPAA violations. The settlement "eclipses the previous high of $5.5 million paid to OCR in 2016."

The data breach at issue resulted from the exposure of electronic protected health information of almost 79 million people, stemming from a series of cyberattacks. Anthem discovered that cyber-attackers had gained access to IT systems via an "undetected continuous and targeted cyberattack for the apparent purpose of extracting data, otherwise known as an advanced persistent threat attack." After Anthem filed its breach report with OCR, it discovered that cyber-attackers had infiltrated its system through spear phishing emails to which at least one employee responded, thus opening the door to further attacks. The health and personal information of the 79 million individuals included names, social security numbers, medical identification numbers, addresses, dates of birth, email addresses, and employment information.

Per OCR's press release, "In addition to the impermissible disclosure of ePHI, OCR's investigation revealed that Anthem failed to conduct an enterprise-wide risk analysis, had insufficient procedures to regularly review information system activity, failed to identify and respond to suspected or known security incidents, and failed to implement adequate minimum access controls to prevent the cyber-attackers from accessing sensitive ePHI, beginning as early as February 18, 2014."

The settlement should serve as a warning and reminder to covered entities and business associates to review, update, and fully implement their HIPAA privacy and security policies and procedures; to conduct periodic security risk and gap analyses, as required by the HIPAA Security Rule; and to ensure ongoing monitoring processes are in place.

HHS and ONC Update Security Risk Assessment Tool to Assist Covered Entity and Business Associate Compliance with HIPAA Security Rule

On October 16, 2018, the Department of Health & Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC) and the HHS Office for Civil Rights (OCR) announced that they have updated the Security Risk Assessment (SRA) Tool "to make it easier to use and apply more broadly to the risks to health information."

The updated SRA Tool includes new functionality and may be used by covered entities and business associates as a tool to assist in performing risk assessments as required by the HIPAA Security Rule.

If you would like more information or assistance with developing, updating or implementing your HIPAA compliance program, contact:

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