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Health Law UPDATE

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FEDERAL UPDATE

DHHS Recommends Rx Naloxone to Patients at High Risk for an Opioid Overdose

On December 19, 2018, the U.S. Department of Health & Human Services (HHS) published a notice entitled, "HHS Recommends Prescribing or Co-Prescribing Naloxone to Patients at High Risk for an Opioid Overdose."

In the notice, HHS advised that Adm. Brett P. Giroir, M.D., the Assistant Secretary for Health and Senior Advisor for Opioid Policy, released a guidance document "for healthcare providers and patients detailing how naloxone – the opioid overdose reversal drug – can help save lives and should be prescribed to all patients at risk for opioid complications, including overdose."

HHS further advised that:

> "To reduce the risk of overdose deaths, the guidance released [on December 19, 2018] reinforces and expands upon prior CDC guidelines. It recommends that clinicians prescribe or co-prescribe (prescribed in conjunction with additional medication) naloxone to individuals at risk for opioid overdose, including, but not limited to: individuals who are on relatively high doses of opioids, take other medications which enhance opioid complications or have underlying health conditions. By co-prescribing, or prescribing naloxone to at-risk individuals, patients and their loved ones could be better equipped for [a] possible complications of overdose, including slowed or stopped breathing. Clinicians should also educate patients and those who are likely to respond to an overdose, including family members and friends, on when and how to use naloxone in its variety of forms."

The notice and guidance are further evidence of our nation's focus on addressing the opioid epidemic.

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CMS Updates Guidance Regarding Medicare Preclusion List

The Centers for Medicare & Medicaid Services (CMS) recently published an update to guidance CMS previously provided regarding the Medicare Preclusion List. In April 2018, CMS published a rule rescinding the Medicare enrollment requirement for contracted providers that receive payment from certain Medicare plans, and rescinded a requirement that providers who prescribe drugs must enroll in Medicare in order for their prescriptions to be covered by Medicare Part D. In the alternative, in order for contracted and non-contracted providers to receive payment from Medicare for services provided to patients enrolled in those plans, and in order for a prescriber of drugs to be entitled to reimbursement under Medicare Part D, the provider and/or prescriber must not be included on the Preclusion List.

In November 2018, CMS published a memo providing guidance regarding how Medicare plans should implement and comply with Preclusion List requirements. According to the memo, the Preclusion List consists of providers who are currently revoked from Medicare or are under an active reenrollment bar. It also includes providers who, according to CMS, have displayed conduct that is detrimental to the Medicare program's best interests, or providers who have engaged in conduct for which CMS could have revoked enrollment had they been enrolled in Medicare. Before being placed on the Preclusion List, providers are entitled to written notice and certain appeal rights. CMS will make the Preclusion List available on its website and update it on a monthly basis. Medicare plans must remove any contracted providers who are on the Preclusion List and notify patients enrolled in Medicare who have received care or a prescription from a provider on the Preclusion List within the last 12 months. In the recently published updated guidance, CMS provided a revised sample notice to beneficiaries, and provided answers to certain frequently asked questions regarding the Preclusion List that were posed since the initial guidance was published by CMS. More information on the CMS Preclusion List may be found here.

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OIG Finds Permissible Waiver of Cost Sharing By Charitable Pediatrics Clinic

The U.S Department of Health & Human Services, Office of Inspector General (OIG) issued an advisory opinion on January 9, 2019, on whether an arrangement waiving certain cost-sharing amounts at a charitable pediatrics clinic was subject to sanctions for potentially generating prohibited remuneration under the Social Security Act (Act) and violating the Federal Anti-Kickback Statute.

OIG advised that, based on the clinic's efforts and conduct in waiving cost-sharing amounts, it would not impose sanctions under the Act. The OIG found that the risk of fraud and abuse was minimal under the Act, due to the conduct of the clinic and safeguards it has put in place. The OIG, in drawing its conclusion, reviewed such items as how the clinic determines eligibility guidelines for its patients, how many patients receive

a waiver, the clinic's certification that the cost-sharing waiver is not part of a solicitation or advertisement, if the clinic offered no financial incentive for its doctors or health care providers to induce patient referrals to the clinic, if the clinic did not list the monies waived as bad debt or pass the cost on to federal health programs, or if the clinic considers the patient's medical condition or insurance status when determining eligibility of services or course of treatment. Though the arrangement did not fall within an exception, the OIG advised it would not pursue sanctions due the conduct of the clinic and therefore lacked the "requisite intent to induce or reward referrals of Federal health care programs."

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Proposed Law Seeks to Disrupt the Drug Market and Make Prescriptions More Affordable

The Prescription Drug Price Relief Act[1] was proposed to Congress in early January 2019. Spearheaded by Vermont Senator Bernie Sanders, this bill seeks to reduce the price of brand-name drugs in America, making prices more consistent with drug prices of other countries[2]. If the bill passes in its current form, the Department of Health and Human Services (HHS) would be tasked with reviewing each brand name drug at least once a year, and making determinations as to whether or not its price is "excessive."

In order to make its determination about whether a drug is "excessively priced," the bill seeks to have the HHS compare brand-name drug prices with comparable drugs in five chosen countries: Canada, the United Kingdom, France, Germany, and Japan.

Any person would be able to petition the HHS to conduct a review of a certain brand-name drug. The HHS would be obligated to make its determination within 90 days of these petitions, with the limit that each drug petitioned would only need to be reviewed once a year. Under the proposed law, all these petitions along with all of the HHS's determinations would be made publicly available.

According to the bill, the appropriate price of the brand-name drug may not be no more than the median price of the drug in the above five countries. If a brand-name drug is in fact found to have an "excessive" price, as determined by the HHS, the drug companies will face severe penalties. Most notably, and likely the one that would hurt the drug companies the most, is the HHS's ability to grant other companies non-exclusive rights to use the patent of that drug, and to rely on the test data already in place for the drug. Further, government-granted exclusivities will be immediately waived and voided. This means that any person or company would be able to make, use, sell, or import the brand-name drug and disrupt the marketplace, so long as the HHS accepts his/her/its request to use the previously protected drug patent.

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Key Takeaways from Recent IRS Guidance on the New Excise Tax on Nonprofit Executive Compensation

On December 31, 2018, the Internal Revenue Service (IRS) issued a notice to provide interim guidance on the applicability of Section 4960 of the Internal Revenue Code, enacted in December 2017 as part of the Tax Cuts and Jobs Act. Section 4960 imposes a 21% excise tax on nonprofit executive compensation over $1 million paid by tax-exempt employers to covered employees for tax years beginning after December 31, 2017. Under the law, covered employees for purposes of the excise tax are current or former employees who are in the top five highest compensated employees of the organization in any tax year beginning after December 31, 2016. The 21% excise tax also applies to excess parachute payments, defined as payments contingent on an employee's separation from employment and where the total payment is at least three times the employee's average annual taxable compensation in the preceding five years. The tax applies to the portion of the parachute payment that exceeds the average annual compensation.

The IRS Notice clarifies that a group of related tax-exempt organizations, such as a multi-corporate health care system, may not have a single set of covered employees for the entire group of organizations, unless there is one common employer for all employees. Thus, a complex nonprofit system may have several entities each with their own five highest compensated employees that could trigger the excise tax for the system. Multiple entities within an organization may be responsible for a portion of the excise tax, both as an employer of its own covered employees and as a related organization. An organization is related if it controls more than 50% of the tax-exempt organization, or is more than 50% controlled by the tax-exempt organization.

The Notice further explains that if any individual is one of the organization's five highest paid in any tax year beginning after December 31, 2016, the individual is deemed a covered employee permanently, even if his or her compensation is less than $1 million. The excise tax would apply if that covered employee is ever paid an excess parachute payment. Tax-exempt employers must identify and log covered employees and their compensation each year and maintain such logs indefinitely.

Compensation for purposes of determining a covered employee is, as explained in the Notice, any remuneration that, when paid, is treated as wages subject to federal income tax withholding. This includes deferred compensation when it becomes vested, at which point it is deemed paid. The vested compensation and any earnings on that compensation are excluded from the excise tax if the vesting and earnings occurred before the effective date of the tax. Compensation is based on compensation paid by the tax-exempt employer and by related organizations, even if the related organizations are not tax-exempt. The tax-exempt employer must determine how much compensation is imputed to employees from related organizations. The law provides that compensation paid to a licensed medical professional for medical services is excluded for purposes of determining covered employees and amounts subject to the tax. The Notice clarifies, however, that only compensation paid for the "direct performance" of medical services to patients is disregarded, while compensation for teaching, research, or administration is included.

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STATE UPDATE

New Jersey Legislative Update

Department of Health Awarded $2.3 Million to Enhance Pediatric Mental Health Care through Telehealth—On January 10, 2019, the New Jersey Department of Health (DOH) was awarded more than $2.3 million over a five-year period from the federal Health Resources and

Service Administration to enhance primary, behavioral and mental health care for children and adolescents through telemedicine and educational programs. The grant will provide technical assistance to primary care providers on screening, early identification, diagnosis, referral, and treatment of children and adolescents with mental and behavioral health disorders using telehealth. Telehealth is the provision of health care remotely by means of telecommunications technology, such as video conferencing and internet technology. The grant will specifically assist the Pediatric Psychiatry Collaborative, a network of nine regional hospital-based hubs funded by the New Jersey Department of Children and Families that screen, identify, and care for children with mental health concerns, and offer telehealth services. New Jersey First Lady Tammy Murphy, who has been active in the Murphy administration's health care efforts, stated that "[E]xpanding integrated treatment options with telehealth will alleviate some of the logistical challenges associated with receiving care and encourage those who are not receiving treatment to seek help."

New Bill Introduced to Prohibit Pre-Approval of Cancer Treatments—On December 6, 2018, Bill S3251 was introduced in the New Jersey Senate to prohibit pre-approval or precertification of cancer treatments, tests, procedures, and prescription drugs covered under health benefits or prescription drug benefits plans. The Bill had previously been introduced in the New Jersey Assembly. The Bill prohibits health insurers, third-party administrators, pharmacy benefits managers, and the State Health Benefits Program and the School Employees' Health Benefits Program from requiring the pre-approval or precertification of treatments, tests, procedures, or prescription drugs covered under a health benefits or prescription drug benefits plan when prescribed for a covered individual who has been diagnosed with cancer. The purpose of the Bill is to ensure that cancer patients are not burdened with technical requirements by health benefits providers which employ utilization management review systems that slow down medical care.

Legislature Passes Bill To Establish Reciprocity Requirements for Out-of-State Certified Nurse Aides—On December 17, 2018, the New Jersey Senate and the New Jersey Assembly passed Bill A2442 which establishes reciprocity requirements for out-of-state certified nurse aides to practice in New Jersey. The Bill now awaits Governor Murphy's signature. Under the Bill, an individual certified as a nurse aide by another state or territory of the United States may apply to have that certification entered on the registry established and maintained by the Department of Health, provided that: (1) the Department of Health receives documentation from the other state or territory that the applicant holds a current, valid certification as a nurse aide in the state or territory; (2) the applicant has not been convicted of any crimes and has no documented findings of abuse, neglect, or misappropriation of resident property in the other state or territory; (3) the applicant complies with applicable criminal history record background check requirements; and (4) the applicant has completed within the preceding 24 months the amount of continuing education hours required by regulation for a nurse aide; or the applicant has the equivalent of at least two years of full-time employment in the other state or territory as a nurse aide and the most recent date of such employment is within the 24-month period immediately preceding the date of the application.

New Bill Introduced Requiring Medical Marijuana Reporting to Prescription Monitoring Database—On December 17, 2018, Bill A4824 was introduced in the New Jersey Assembly requiring written instructions for, and dispensations of, medical marijuana to be reported to the New Jersey prescription monitoring database. The Bill specifically requires medical marijuana alternative treatment centers to submit certain information concerning medical marijuana dispensed to registered qualifying patients or their designated caregivers to the prescription monitoring program administered by the Division of Consumer Affairs in the Department of Law and Public Safety. The information will include the form, strain, quantity, and potency of medical marijuana dispensed, the patient's name and registry identification number, the primary caregiver's name and registry identification number if the medical marijuana is dispensed to the caregiver, and the name of the physician and the alternative treatment center. Additionally, the Bill requires alternative treatment centers to check a patient's prescription monitoring information prior to dispensing medical marijuana to the patient or the patient's primary caregiver to determine whether the patient was dispensed medical marijuana from any alternative treatment center within the past 30 days.

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Brach Eichler In The News

John D. Fanburg commented on the future of Obamacare in a January 28 article in *NJBIZ*.

On January 23, **Riza Dagli**, **Mark Manigan**, and **John Fanburg** spoke at the quarterly meeting of the New Jersey Association of Ambulatory Surgery Centers (NJAASC). Their topics included regulatory and legislative updates and a special presentation, "Billing Error or Criminal Intent?."

In early January, **Mark Manigan** was quoted extensively in the media in his representation of HealthPlus.

To view a full listing of recent news items and to read the articles mentioned above, please click here.

HIPAA CORNER

Covered Entities Must Submit OCR Breach Logs by March 1

Under the HIPAA Breach Notification Rule, covered entities such as health care providers and insurance companies must make written notification to affected individuals following a breach of "unsecured" protected health information (PHI). Unsecured PHI is PHI "that has not been rendered unusable, unreadable, or indecipherable to unauthorized persons through the use of a technology or methodology specified by the Secretary [of the DHHS] in guidance." Typically, this refers to PHI that has not been fully destroyed by methods such as shredding or that has not been encrypted. The rule contains specific timeframes in which such notifications must be made.

In addition to notifications to affected individuals following a breach incident, covered entities are required to submit breach notification to the U.S. Department of Health & Human Services (DHHS). The timing of notification to the DHHS depends on the size of the breach. Specifically:

- For a breach event affecting 500 or more individuals, covered entities must notify the Secretary of DHHS "without unreasonable delay and in no case later than 60 days following a breach." (It should be noted that breach events affecting more than 500 individuals in a state or jurisdiction also must be reported to major media outlets, as required under the Breach Notification Rule.)

- For each breach incident in a calendar year that affects fewer than 500 individuals, covered entities must submit notification to the DHHS on an annual basis, "no later than 60 days after the end of the calendar year in which the breaches are discovered." *Id*. As such, notification for such breaches in calendar year 2018 must be submitted no later than March 1, 2019.

Notification to the DHHS should be made via the DHHS breach portal, found here.

If you need assistance in managing a breach incident or making any required reporting, please contact:

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Be Reminded (or Informed) that HIPAA Contains Criminal Penalty Provisions

The *National Law Review* has reported that "a Georgia-based physician who previously pleaded guilty to criminal violations" of HIPAA entered into a deferred prosecution agreement in which he received six months of probation. By way of background, the physician pleaded guilty to misdemeanor wrongful disclosure of protected health information (PHI) and, as a result of HIPAA's criminal penalty provisions, was facing a potential sentence of up to one year in prison. The Massachusetts Department of Justice prosecuted the physician in connection with its investigation of pharmaceutical company Aegerion relating to the mis-branding of a prescription drug called Juxtapid. Allegations relating to the physician included that he allowed sales representatives of the drug company to access "confidential medical information of patients who were not diagnosed with a condition treated by Juxtapid to identify potential candidates for the drug, in violation of HIPAA's prohibition on wrongful disclosures of health information."

The deferred prosecution agreement is a reminder that HIPAA contains both civil money penalties and criminal penalties for violations resulting from knowingly obtaining or disclosing PHI. "A person who knowingly obtains or discloses individually identifiable health information in violation of the Privacy Rule may face a criminal penalty of up to $50,000 and up to one-year imprisonment. The criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses, and to $250,000 and up to 10 years' imprisonment if the wrongful conduct involves the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain or malicious harm." At the federal level, criminal HIPAA violations are prosecuted by the federal Department of Justice, while state Departments of Justice may prosecute at the state level.

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

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[1] *https://www.sanders.senate.gov/download/prescription-drug-price-relief-act-2018?id=B06E31B7-D178-4019-800F-E21D72FEA9CE&download=1&inline=file.*
[2] *https://www.sanders.senate.gov/download/one-pager-prescription-drug-price-relief-act-2018?id=84D5977E-AA74-4AC7-BEB9-8C30095B3C54&download=1&inline=file.*

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