June 2019

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with May through June 2019 articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented to HLS members for general information only and do not constitute legal advice from The Florida Bar or its Health Law Section. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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COMPLIANCE UPDATES

New DOJ Guidance on Evaluating Corporate Compliance Programs

On April 30, 2019 the U.S. Department of Justice ("DOJ") updated its guidance on evaluating corporate compliance programs. While the DOJ acknowledged that there is no "rigid formula" when it comes to assessing compliance programs, the guidance directed prosecutors to ask three fundamental practical questions in their evaluation:

(i) Is the corporation's compliance program well designed?
(ii) Is the program being applied earnestly and in good faith? and
(iii) Does the corporation's compliance program work in practice?

These three fundamental questions are further broken down into twelve specific sub-areas for assessment, ranging from policies and procedures to remediation activities and third-party management. According to the DOJ Press Release:

> Part I of the guidance document discusses various hallmarks of a well-designed compliance program relating to risk assessment, company policies and procedures, training and communications, confidential reporting structure and investigation process, third-party management, and mergers and acquisitions. Part II details features of effective implementation of a compliance program, including commitment by senior and middle management, autonomy and resources, and incentives and disciplinary measures. Finally, Part III discusses metrics of whether a compliance program is in fact operating effectively, exploring a program's capacity for continuous improvement, periodic testing, and review, investigation of misconduct, and analysis and remediation of underlying misconduct.

The new guidance is an excellent tool for companies undergoing a government investigation, as well as for companies that are either developing or enhancing their compliance programs.[1]

Submitted By: **Christian Perez Font, Esq., *Thinkeen Legal, P.A.***

FRAUD & ABUSE UPDATES

Florida Healthcare Fraud & Abuse Enforcement

According to a U.S. Department of Justice ("DOJ") Press Release, on May 20th, 2019, the owner of a Miami home health care agency was sentenced to 30 months in prison for his participation in a scheme that involved the submission of false and fraudulent claims for home health care services that were never provided totaling $1 million.[2] In addition to the prison term, the owner was ordered to pay $951,473.00 in restitution, jointly and severally with his co-conspirators, and to forfeit the same amount.

On June 13, 2019, the DOJ also announced that the owner of American Pain Management, a company that operated pain clinics in Broward and Palm Beach counties, and who also owned Pacific Pharmacy located in Miami, was sentenced to 78 months in prison followed by three years of supervised release for his role in a $2.2 million Medicare fraud scheme.[3] According to the DOJ, the owner of these two entities admitted to submitting fraudulent claims totaling $1.2 million, as well as disguising his ownership of Pacific Pharmacy to circumvent restrictions placed by the Florida Legislature prohibiting pain clinics from dispensing controlled substances directly from a clinic.

Submitted By: **Christian Perez Font, Esq., *Thinkeen Legal, P.A.***

South Florida Patient Recruiter Sentenced for Role in Home Health Kickback Scheme

On May 8, 2019, a South Florida woman received a seven-year prison sentence for her role as a patient recruiter in a kickback scheme that led Medicare to pay out roughly $1.6 million for home health care services.[4]

Following a four-day trial in February, a jury found Yamilet Diaz of Hialeah guilty on one count of conspiracy to defraud the United States and four counts of receiving health care kickbacks. Prosecutors presented evidence at trial that between February 2012 and August 2013, Diaz received at least $710,000.00 from her participation in the scheme by referring Medicare beneficiaries to five South Florida home health agencies. As a result, Medicare issued more than $1.6 million in payments to the home health agencies for claims of service for those patients.

Denying Diaz's request for a more lenient sentence, U.S. District Judge James I. Cohn ordered Diaz to serve three years of supervised release and to pay $1.6 million in restitution in addition to her prison sentence. Diaz is also restricted from working for health care businesses.

This case was filed as part of the Medicare Fraud Strike Force.

Submitted By: **Erin J. Hoyle, Esq., *Carlton Fields***

Recent Enforcement Trends: Compounding Pharmacies and Pain Management Clinics

Several May and June 2019 actions have revealed interesting trends in health care fraud and abuse enforcement, particularly: (1) more scrutiny over compounding pharmacies, specifically patient prescriptions and treatments for medical necessity and correctness; and (2) deeper examinations into pain management clinic referral sources for illegal kickbacks and sufficiency of patient examinations before prescribing controlled substances, especially opioids.

Compounding Pharmacies

Compounding pharmacies, as defined by the Food and Drug Administration ("FDA"), are pharmacies and pharmacists that combine, mix or alter ingredients to create a medication tailored to the needs of an individual patient. Compounded medications are prescribed when standard, FDA-approved drugs are unsuitable for a patient and are generally more expensive and reimbursed at a higher rate by federal and private insurance companies.

In May 2019, the Department of Justice ("DOJ") charged ten workers from Alabama-based Global Compounding Pharmacy, including a nurse practitioner, pharmacist, the pharmacy's owners, and a marketer, in connection with a $200 million prescription drug fraud scheme.[5] The indictment alleges that Global Compounding Pharmacy billed for medically unnecessary prescription drugs and compounded medications (typically opioids) that often were never purchased or distributed to beneficiaries. To maximize profits, the company also allegedly engaged in additional fraudulent practices including automatically refilling and billing for prescriptions, regardless of patient need, and waiving co-pays to incentivize patients to accept the unnecessary refills.

Another example of governmental focus on compounding pharmacies is a June 2019 case from the Northern District of Oklahoma, in which three physicians and five marketers allegedly engaged in a conspiracy to unlawfully pay kickbacks and bribes to physicians in exchange for the physicians writing compounding prescriptions to specific compounding pharmacies controlled by two of the named defendants.[6] The indictment also alleges that physicians were provided pre-printed prescription pads that listed compounding formula choices. Participating physicians allegedly checked a box with their preferred selection and then faxed it directly to the associated pharmacies, rather than writing a prescription tailored to the patient who could then take it to a pharmacy of their choice.

The above cases underscore the importance of closely monitoring the practices and policies of compounding pharmacies, implementing rigorous internal compliance protocols, and promptly and effectively responding to inquiries from federal agencies or the DOJ.

Pain Management Clinics

In part due to the ongoing national opioid epidemic, pain management clinics continue to be a target of government health care fraud investigations and enforcements. In the last eighteen (18) months, the DOJ has established the Opioid Fraud and Abuse Detection Unit, a new pilot program that aims at utilizing data analytics to combat the opioid epidemic. Under this program, each United States Attorney's office has been directed to designate an Assistant United States Attorney to act as an opioid coordinator and focus on prosecuting opioid-related offenses. The program also established the Prescription Interdiction Litigation Task Force, a program that coordinates civil and criminal enforcement tools to combat the opioid epidemic.

As part of these efforts, in June 2019, a Florida pain management clinic owner was sentenced to 78 months in prison for his role in a $2.2 million Medicare fraud scheme (see Florida-specific update on this topic, above). In another recent case, charges were filed against a South Carolina chiropractor and the pain management clinics and urine drug testing laboratories he owned or managed[7] for engaging in illegal financial relationships and for providing medically unnecessary

services and items, including urine drug testing and steroid injections and prescriptions for opioids and lidocaine ointment.

Federal and state level scrutiny of entities and providers involved in the pain management industry are likely to continue. To avoid DOJ scrutiny, entities and providers in the pain management industry should proactively implement policies that track and account for a prescriber's total aggregate opioid prescription history to ensure proper documentation of necessity of such prescriptions; perform periodic reviews and/or audit of patient files; carefully evaluate new patients on initial visits and document diligence undertaken prior to prescribing an opioid; and review basic demographic and contact information of patients to ensure that an entity or physician is not unknowingly being targeted by drug-seeking individuals.

As these recent indictments and settlements range from just $100,000.00 in damages to $1 to 2 million, this is indicative of the fact that small and large providers alike need to take compliance and fraud and abuse safeguards seriously.

Submitted By: **Jeff Mustari, Esq., *Southern Health Lawyers, LLC***

The Travel Act: Federal Prosecution for State Law Violations[8]

If you thought that your clients are out of the reach of the federal government when they are in an arrangement that could constitute remuneration in exchange for referrals because they do not treat patients covered by Medicare, Medicaid, or Tricare, think again. The Travel Act is the Department of Justice's ("DOJ") new tool to fight kickbacks occurring in the context of private payers.

Kickback Prohibitions in General

The Federal Anti-Kickback Statute ("AKS") only prohibits the payment of "remuneration" for referrals involving federal healthcare programs (e.g., Medicare, Medicaid, and Tricare).[9] Under the AKS, referral cases with private insurance companies are beyond the federal government's reach.[10]

In Florida, the Patient Brokering Act (the "Act") makes it illegal for any person to offer, pay, or solicit benefits or kickbacks in exchange for referrals.[11] This Act applies to kickbacks, regardless of the payment source.[12] Section 456.054, Florida Statutes, specifically prohibits healthcare providers from offering, paying, or soliciting kickbacks for patient referrals.[13]

What is the Travel Act?

The Travel Act, passed in 1961, makes it a federal crime to distribute the proceeds of, commit, or promote unlawful activity across state lines.[14] The Travel Act defines unlawful activity to include gambling, bribery, and other illegal monetary exchanges.[15] The Travel Act is not limited to particular types of crimes, so it gives the federal government the ability to criminalize a wide range of illegal conduct occurring across state lines.[16]

Recently, physicians and others accused of participating in illegal kickback schemes, even involving private payers, have been charged or indicted federally by the DOJ under the Travel Act.[17] Even if a party is not in violation of the AKS, the federal government may still have jurisdiction over that individual if the conduct or activity spans across state lines.[18]

Indictments under the Travel Act

In May, 2019, in the Eastern District of New York, two individuals were indicted under the Travel Act.[19] Christopher Walker, M.D., a Florida-licensed physician, and his former employer, Wesley Blake Barber, are alleged to have induced individuals to undergo vaginal mesh removal procedures in order to profit from lawsuits against surgical mesh manufacturers.[20] The defendants allegedly falsely defined the risks of the surgery to the victims, inferred that the victims would have to travel to visit specific doctors, and deceived the victims into believing that their health insurance would cover surgery expenses.[21]

The federal government's charges against the defendants included Wire Fraud Conspiracy, Wire Fraud, Travel Act Conspiracy, and violations of the Travel Act.[22] Under the Wire Fraud Conspiracy and Wire Fraud charges, the government contended that the defendants "knowingly and intentionally" devised the scheme to benefit off of lawsuit settlements and misrepresented the facts to the patients through multiple e-mails.[23] Under the Travel Act Conspiracy and Travel Act violations, the defendants were charged with "knowingly and willfully" conspiring to use facilities of interstate commerce to carry out unlawful activity in violation of the laws of the state where these acts were committed,[24] specifically the Florida kickback prohibitions.[25] The overt acts used to indict the defendants under the Travel Act included the victims' travel between New York and Florida and the checks that were issued for the surgeries.[26]

Similarly, in 2017 in the Southern District of Florida, Eric Snyder, the owner of a treatment center and sober home, and Christopher Fuller, an alleged patient broker, were federally charged with conspiracy to commit healthcare fraud.[27] In that case, claims were submitted to private insurance companies for services that were not allegedly medically necessary or were never provided.[28] The defendants also allegedly engaged in client brokering and offered kickbacks to patients for participating in rehabilitation programs.[29] On June 7, 2018, the defendants were subsequently federally indicted for healthcare and wire fraud and for being in violation of the Travel Act.[30] The Travel Act was implicated because the defendants allegedly defrauded health insurance companies of $20,190,941 dollars, illegally recruited patients, and paid kickbacks in violation of the Act.[31]

Based on the above, attorneys and their healthcare clients should be aware that the DOJ may prosecute providers for alleged kickback schemes even though they may not involve federal healthcare programs. Healthcare companies should reevaluate their marketing programs in order to ensure they are fully compliant with both federal and state law. Use of the Travel Act federally to prosecute state law violations changes the landscape considerably.

Submitted By: **Lester J. Perling, Esq., *Nelson Mullins Broad and Cassel***

LEGISLATIVE UPDATES

Florida Patient Brokering Act Amended- Does It Clarify The Act Or Create New Issues?

The Florida Legislature recently passed HB 369 (the "Bill"), which would tweak an important provision of the Florida Patient Brokering Act, Section 817.505, Florida Statutes ("Patient Brokering Act"). It seeks to clarify the exception to the Patient Brokering Act which incorporated by reference the criminal provisions of the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)) pertaining to illegal remuneration) (the "AKS") and its safe harbor regulations. However, the attempt to clarify the exception may have made it less clear.

The applicable exception in the Patient Brokering Act, Section 817.505(3)(a), currently states that:

> *(3) This section shall not apply to:*
>
> *(a) Any discount, payment, waiver of payment, or payment practice not prohibited by 42 U.S.C. s. 1320a-7b(b) or regulations promulgated thereunder.*

The revision in the Bill enacted by the Legislature on May 3, 2019, states that:

> *(3) This section shall not apply to the following payment practices:*
>
> *(a) Any discount, payment, waiver of payment, or payment practice expressly authorized by 42 U.S.C. s. 1320a-7b(b)(3) or regulations adopted thereunder.*

So, what does the change mean? And why was the language changed?

The Summary Analysis of the Bill states that it *"[c]larifies the application of the patient brokering statutes to certain payment practices . . . "* Unfortunately, it does not accomplish this objective. The current phrase "*not prohibited by [the federal Anti-Kickback Statute]*" is somewhat vague in that the federal AKS is intent-based. To determine whether a business or payment practice is "*not prohibited*," one would need to analyze the intent of the parties and attempt to apply extensive federal case law to the specific facts and circumstances. However, the reference to "*or regulations promulgated thereunder*" incorporates the federal safe harbor regulations. One interpretation is that if conduct meets the criteria of an applicable federal safe harbor regulation, it will not violate the Patient Brokering Act.

The change to "*payment practices . . . **expressly authorized** by* [the federal AKS]" renders the exception less clear in that the AKS is a criminal statute that prohibits certain business and payment practices. The AKS does not expressly authorize any business or payment practices.

The safe harbor regulations adopted under the AKS describe business and payment practices that would not be subject to criminal prosecution under the AKS. They too do not expressly authorize business or payment practices. In light of the expansive language in the AKS and broad prosecutorial discretion, the safe harbor regulations were adopted to describe business and

payment practices that, although they potentially implicate the AKS, would not be treated as a criminal offense under the statute.

The Committee Analysis raises another issue when it states that *"[t]he federal provisions only apply to federally funded programs . . ."* The statement raises the question whether the federal safe harbor regulations to the AKS, by virtue of being incorporated into the Patient Brokering Act, apply to business and payment practices applicable to private insurance payors. The Staff Analysis suggests that the safe harbor regulations to the AKS incorporated into the Patient Brokering Act do not apply to patient brokering related to private insurance policies and coverage. In *State v. Kigar*, the Court recently held that the AKS, including its *mens rea* standard, was incorporated by reference into the Patient Brokering Act.[32] The Staff Analysis to the Bill indicated that this decision results in "*uncertainty on whether [the Patient Brokering Act] will apply to private insurance-related patient brokering . . .*" Unfortunately, the revisions to the Patient Brokering Act contained in the Bill do not serve to clarify this issue.

If a provider treats patients under both federally funded programs and patients with private insurance, would the provider be immune from criminal prosecution under federal law but subject to prosecution under the Patient Brokering Act for the same business or payment practice? The Florida Supreme Court has already reviewed a similar issue in the conflict between the Florida Medicaid Anti-Kickback Statute and the AKS and determined that the doctrine of implied conflict preemption applies where it is impossible to comply with both the state and federal regulations or where the state law is an obstacle to accomplishing the full purpose and objectives of Congress.[33] [State v. Harden, 938 So.2d 480 (Fla. 2006), cert denied, 127 S.Ct. 2097, 167 L.Ed.2d 812 (2007)]. It should be noted that the Harden case involved a conflict between the Florida Statute governing Medicaid, a joint federal/state program, and the federal AKS, which applies to the same program.

While the overall objectives of the Bill may be laudatory, the change to the Patient Brokering Act does not provide clarity to providers seeking to comply, and prosecutors and payors seeking to enforce, the law. A court may ultimately determine whether the revision has met the stated objective of clarifying the Act or whether it has rendered the Act less clear and raised additional issues with respect to its application to providers who endeavor to comply with both the federal and state law.

As of the date of this update, the Bill has not been signed into law or vetoed by the Governor. It is unclear if and when it will become law. And if and when it becomes law, it is unclear what the change means and how it is to be applied.

[Editor's Note: This Bill was signed by the Governor on June 27, 2019, and is scheduled to take effect on July 1 2019].

Submitted by: William J. Spratt, Jr., *Akerman LLP*

Palm Beach County Sober Homes Task Force Legislation Poised to Go into Effect

After passing with unanimous support in the House and Senate, Florida House Bill 369 (HB 369)[34] is set to become effective as of July 1, 2019. Based on recommendations from Palm Beach County's Sober Home Task Force (the "Task Force"),[35] HB 369 will continue the Task Force's efforts to improve regulation for Florida's substance use disorder ("SUD") treatment industry. Some of HB 369's updates are explained below.

Patient Brokering Act Revision Clarification

Currently, it can be argued that Florida's patient brokering statute ("PBA")[36] does not apply to payment practices "not prohibited" under the federal anti-kickback statute ("AKS").[37] HB 369 amends the PBA so that the statute will not apply to any payment practice "expressly authorized" under the AKS, which may address instances where a court interprets Florida's PBA to only apply to federally funded programs.

"PHP" Housing Must be FARR Certified

HB 369 now requires the residential component (*i.e.*, the sober living residence) of a Day or Night Treatment with Community Housing, or "PHP," license to be certified by the Florida Association of Recovery Residents ("FARR").[38] Due to administrative ruling by Florida's Department of Children and Families ("DCF") last year, PHP community housing became exempt from FARR certification requirements.[39] HB 369 closes that loophole. Additionally, the housing components would need a certified recovery residence administrator to actively manage them and they would be subject to the referral restrictions of Section 397.4873, Florida Statutes.[40]

Right to Discharge or Transfer Resident Supersedes Landlord and Tenant Rights

The bill allows a FARR-certified recovery residence to transfer or discharge residents in accordance with their approved discharge policies under certain circumstances related to the resident's welfare or needs, or the welfare and needs of other residents. This right to discharge or transfer a resident supersedes any landlord and tenant rights and obligations under Chapter 83, Florida Statutes.[41]

Limited Exemptions from Disqualification for Level 2 Background Screenings

The bill also gives DCF (or AHCA) the authority to grant limited exemptions from disqualification to work solely in mental health treatment programs and facilities, in recovery residences, or in those programs or facilities that treat co-occurring SUD and mental health disorders, to an employee otherwise disqualified from employment under Section 435.07, Florida Statutes.[42]

Deceptive Marketing Practices

For treatment facilities that contract with a marketing provider to provide referrals to the recovery residence, it will now be a contractual requirement for the marketer to disclose the nature of the

referral and the list of DCF's licensed service providers and certified recovery residences. This will provide people in recovery with greater protections from deceptive marketing practices.

Felony Misrepresentation in DCF Application

Currently, it is a first-degree misdemeanor to fail to disclose or to make false or fraudulent statements in an application for DCF licensure. HB 369 increases criminal penalties for these misrepresentations from a first-degree misdemeanor to a third-degree felony.

Clinical Supervisors Must be "Qualified Professionals"

After the bill takes effect, all clinical supervisors must meet the definition of a "qualified professional," as that term is defined in Section 397.311(34), Florida Statutes.[43] That is, only a licensed physician, physician assistant, psychologist, mental health professional, advanced practice registered nurse, or a certified SUD services provider with a bachelor's degree can serve as a clinical director for a SUD treatment facility.

Peer Specialists

There is no statutory definition of, or requirements for, a peer specialist (as it relates to mental health and SUD). HB 369 creates that definition for peer specialists consistent with DCF's guidelines and guidance documents, and requires peer specialists to be certified, except in limited circumstances, to provide DCF-funded support services.

Submitted By: **Jeffrey Lynne, Esq., and Sam Winikoff, Esq. *Beighley, Myrick, Udell, & Lynne, P.A.***

SUPPORT Act Expands Medicare Secondary Payer Reporting Requirements

In the past few years, the United States has witnessed an increase in opioid misuse and abuse resulting in an uptick on the number of drug overdose deaths nationwide. According to the National Center for Health Statistics, Centers for Disease Control and Prevention, two out of three drug overdose deaths involved an opioid.[44] To tackle the opioid epidemic and with bipartisan support, President Trump signed the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") on October 24, 2018. The law addresses the opioid crisis by confronting a wide range of topics related to Medicaid, Medicare, public health and law enforcement. However, this update will highlight a single provision of the SUPPORT Act – Section 4002 – which expands the Medicare Secondary Payer ("MSP") reporting requirements for health plans and payers.

Section 4002 of the SUPPORT Act amends the MSP provisions of the Social Security Act by requiring group health plans to report primary prescription drug coverage information to the Centers for Medicare and Medicaid Services ("CMS") for calendar quarters beginning on or after January 1, 2020. Previously, reporting prescription drug information was optional for such plans to coordinate benefits with Medicare Part D.[45]

Given this new mandate and the complex relationships for the delivery of prescription drug coverage, it is critical for an organization to determine whether it is considered a responsible reporting entity ("RRE") by CMS. To assist organizations with making the determination, CMS has issued guidance and has recently hosted a webinar to clarify who is considered an RRE. Specifically, in a Frequently Asked Questions and Answers document on the topic published to the CMS website, CMS shares the following:

> *Question 3: In the case of reporting primary prescription drug coverage, which entity will be considered the RRE?*
>
> *Answer 3: The entity considered to be the RRE for the purpose of reporting primary prescription drug coverage will depend on how the plan sponsor structures its contracts for medical, hospital, and prescription drug coverage. It should not be assumed that the RRE will be the entity that has direct responsibility of processing and paying the prescription drug claims. For example, if the plan sponsor contracts with a GHP for hospital, medical and prescription drug coverage, then the GHP is considered the RRE and will be required to report primary prescription drug coverage. In this case, it does not matter whether the GHP administers the prescription drug coverage directly or contracts administration of prescription drug coverage to a third party such as a Pharmacy Benefit Manager (PBM). However, if the plan sponsor contracts with a GHP for medical and or hospital coverage, but then independently contracts with another third party such as a PBM to administer prescription drug coverage, then that third party or PBM is considered the RRE.*[46]

Based on the foregoing, counsel and their clients should review the contractual relationships to determine which entity is responsible for administering the prescription drug coverage and therefore responsible for reporting as the RRE. Additional guidance on the topic can be found on CMS.gov.

It is important to note that noncompliance with these new reporting requirements can result in a monetary penalty of $1,000.00 for each day of noncompliance for each individual for which the information should have been submitted.

Finally, entities that determine that they meet the definition of an RRE and have not previously registered as such with CMS, should register sooner rather than later as they will be required to submit test files as part of the registration process (nNote: The test files must include actual information of covered individuals). Once CMS determines that testing has been successfully completed, the newly registered RRE will be moved from a testing status to a production status. It is only at that time that an RRE can submit actual files to meet the new reporting requirements for calendar quarters starting on or after January 1, 2020.

Submitted By: **Tadena Simpson, Esq, *Envision Options***

Implications of Florida Tackling Rising Drug Costs through Establishing Prescription Drug Importation Programs: *An Overview of Florida's House Bill 19*

House Bill 19, signed into law June 11, 2019 by Governor Ron DeSantis, calls for establishing the Canadian Prescription Drug Importation Program and the International Prescription Drug Importation Program in order to import safe and effective prescription drugs that have the highest potential for cost savings from neighboring Canada and other foreign countries.

Florida joins two other states in the latest state action against rising drug prices. Earlier this year, Vermont and Colorado signed similar legislation into effect allowing for prescription drug importation from Canada. Although the states' legislative initiatives differ, the states all face a common hurdle: getting the plans approved by the Department of Health and Human Services ("HHS"). A waiver allowing international drug importation must be approved by the Secretary of HHS, a right no secretary has ever exercised. The current Secretary of HHS, Alex Azar, publicly dismissed the idea of importing drugs from Canada citing safety concerns and doubting that importing drugs would actually save the U.S. money.

The bill requires the Agency for Health Care Administration ("AHCA") to submit a request for federal approval by July 1, 2020. Critics say the bill lacks a comprehensive plan addressing how federal oversight will impact the state's importation program. Just before the Florida bill signing, Governor DeSantis remarked that, since the passage of House Bill 19, American pharmaceutical companies approached the Florida government with deals of their own. With more states introducing similar legislation, state actors may have increased bargaining power to negotiate discounts on their own.

The Trump administration's commitment to lowering the cost of prescription drugs may be enough pressure for Azar to grant the state waivers for drug importation. However, even with federal approval, Governor DeSantis has acknowledged that the entire process will take at least one year to implement. In the meantime, Florida lawmakers still need to address many of the unanswered obstacles facing the bill's execution.

Submitted By: **Kathleen Premo, Esq., Sanchita Bose, and Lauren Petrin,**
Epstein Becker & Green, P.C.

PRIVACY UPDATES

Is GDPR Relevant in Florida?

In April 2016, the European Union ("EU") adopted a new data protection law called the General Data Protection Regulation 2016/679 ("GDPR") which contains strict technical and organizational provisions and specific requirements for the handling, processing and maintenance of the personal data (including protected health information) of residents of the European Union and the European Economic Area. A notable feature of GDPR is that these strict requirements apply both to individuals and enterprises established in the EU **and also** to individuals and enterprises established outside of the EU but whom handle, process or maintain personal data of EU residents.

While GDPR did not initially receive much attention in the U.S., interest increased steadily (especially among big multinationals) as the enforcement date (May 25, 2018) approached, and is now a topic very much in everyone's mind.

Aside from its extraterritoriality provision, one of the highlights of GDPR is that fines for violations can be quite hefty and can go as high as €20 million or 4% of annual worldwide turnover depending on the type and extent of violation. So the next question surely is: how real is GDPR enforcement?

While there was not much GDPR enforcement during 2018, we have seen a lot of activity in 2019. For instance, in Germany, the data protection authorities for Lower Saxony and Bavaria have recently begun to conduct several GDPR audits, and in January, French authorities levied a €50 million fine against Google for alleged violations associated with ad personalization. Similarly, in January of this year, Portuguese data protection authorities imposed a €400,000.00 fine against Centro Hospitalar Barreiro Montijo for improper controls over the access to medical records and the list continues to grow.

Why is this relevant to Florida practitioners and in particular to health law practitioners? Consider this: according to Visit Florida, the state's official tourism organization, during 2018, Florida received 126.1 million out-of-state visitors of which 10.8 million were international visitors. If we were to assume that the percentage of European visitors is roughly equivalent to the percentage of European immigrants in the state (15% according to Sachs Media[47]) that would mean at least 1.6 million European visitors per year. That number includes both regular tourists (whom can get sick while on vacation) as well as medical tourists. Since we do not have statistics on the number of European visitors getting sick while vacationing in Florida, let's just stay with medical tourists for purposes of our analysis. In this regard, according to a report by the Florida Chamber Foundation,[48] Florida receives between 300,000 and 400,000 medical tourists per year. If we use the same percentage (15%) used above to calculate the number of European medical tourists, that could mean between 45,000 and 60,000 European medical tourists per year. Even if we were to severely slash that number for statistical purposes (i.e. by ten), we are still potentially talking about thousands of European medical tourists visiting Florida in any given year.

Considering these numbers, GDPR is extremely relevant to Florida and healthcare practitioners and their clients should keep this in mind going forward, especially considering that vigorous enforcement seems to be alive and kicking.

Submitted By: Christian Perez Font, Esq., *Thinkeen Legal, P.A.*

TRANSACTIONS UPDATES

Community Health Systems to Divest Two Florida Hospitals

Tennessee-based Community Health Systems ("CHS") announced on May 22, 2019 that it had entered into definitive agreements to sell two of its eighteen Florida hospitals along with their respective assets, physician clinic operations and outpatient services to Adventist Health System

Sunbelt Healthcare Corporation. The two hospitals included in the deal are Heart of Florida Regional Medical Center in Davenport, FL which has a capacity of 193-beds and Lake Wales Medical Center in Lake Wales, FL which has a capacity of 160-beds.

The transactions, which are subject to regulatory approvals, are expected to close in the third quarter of this year. More information about the transaction can be found in CHS' website.[49]

Submitted By: **Christian Perez Font, Esq., *Thinkeen Legal, P.A.***

[1] "Evaluation of Corporate Compliance Programs," U.S. DEP'T OF JUSTICE (Apr. 2019), *available at* https://www.justice.gov/criminal-fraud/page/file/937501/download.
[2] Press Release, U.S. DEP'T OF JUSTICE, Owner of Miami Home Health Agency Sentenced to 30 Months in Prison for Role in Medicare Fraud Scheme (May 20, 2019), *available at* https://www.justice.gov/opa/pr/owner-miami-home-health-agency-sentenced-30-months-prison-role-medicare-fraud-scheme.
[3] Press Release, U.S. DEP'T OF JUSTICE, South Florida Pill Mill Owner Sentenced to Prison for Role in $2.2 Million Medicare Fraud Scheme (June 13, 2019), *available at* https://www.justice.gov/opa/pr/south-florida-pill-mill-owner-sentenced-prison-role-22-million-medicare-fraud-scheme.
[4] *U.S. v. Diaz*, Case No. 18-20473-CR-Cooke, in the United States District Court for the Southern District of Florida.
[5] *See* Press Release, U.S. DEP'T OF JUSTICE, Ten, including Pharmacy Owners, Pharmacist, and Nurse Practitioner, Charged in Over $200 Million Prescription Drug Fraud (May 6, 2019), *available at* https://www.justice.gov/usao ndal/pr/ten-including-pharmacy-owners-pharmacist-and-nurse-practitioner-charged-over-200.
[6] *See* Press Release, U.S. DEP'T OF JUSTICE, Three Physicians and Five Marketers Charged for Violations to Federal Anti-Kickback Statutes (June 13, 2019), *available at* https://www.justice.gov/usao-ndok/pr/three-physicians-and-five-marketers-charged-violations-federal-anti-kickback-statutes.
[7] *See* Press Release, U.S. DEP'T OF JUSTICE, United States Files False Claims Act Complaint Against South Carolina Chiropractor, Pain Management Clinics, Urine Drug Testing Laboratories, and Substance Abuse Counseling Center (June 4, 2019), *available at* https://www.justice.gov/usao-sc/pr/united-states-files-false-claims-act-complaint-against-south-carolina-chiropractor-pain.
[8] Summer Associate Danna Khawam, who is attending Nova Southeastern University – Shepard Broad College of Law, contributed to this article.
[9] 42 U.S.C. § 1320a-7b(b) (2012).
[10] *See id.*
[11] FLA. STAT. § 817.505(1)(a)-(d) (2019).
[12] *See id.*
[13] *Id.* § 456.054(2) (2019).
[14] 18 U.S.C. § 1952 (2012).
[15] *Id.* § 1952(b).
[16] *Id.* § 1952(a).
[17] *See* Indictment at 6-8, *U.S. v. Barber & Walker*, Case No. 19239 (E.D.N.Y. May 23, 2019).
[18] *See* 18 U.S.C. § 1952.
[19] *See* Indictment at 6-8, *U.S. v. Barber & Walker*, Case No. 19239 (E.D.N.Y. May 23, 2019).
[20] *Id.* at 3.
[21] *Id.*
[22] *Id.* at 4-8.
[23] Indictment at 4-6, *U.S. v. Barber & Walker*, Case No. 19239 (E.D.N.Y. May 23, 2019).
[24] *Id.* at 6-8.
[25] *See id.*; FLA. STAT. §§ 456.054, 817.505.
[26] Indictment at 7, *U.S. v. Barber & Walker*, Case No. 19239 (E.D.N.Y. May 23, 2019).
[27] Complaint at 3, *U.S. v. Snyder*, Case No. 17-8268-DLB (S.D. Fla. July 7, 2017).
[28] *Id.* at 14.
[29] *Id.* at 18.
[30] Indictment, *U.S. v. Snyder*, Case No. 18-80111-CR (S.D. Fla. June 7, 2018); Press Release, U.S. DEP'T OF JUSTICE, Southern District of Florida Charges 124 Individuals Responsible for $337 Million in False Billing as Part of Healthcare Fraud Takedown (July 2, 2018), *available at* https://www.justice.gov/usao-sdfl/pr/southern-district-florida-charges-124-individuals-responsible-337-million-false-billing.
[31] FLA. STAT. § 456.054; Complaint at 12, *U.S. v. Snyder*, Case No. 17-8268-DLB (S.D. Fla. July 7, 2017).
[32] *State v. Kigar*, Case No. 16-CF-10364 (Fla. 15th Cir. Ct., Jan 31, 2019).
[33] *State v. Harden*, 938 So.2d 480 (Fla. 2006), cert denied, 127 S.Ct. 2097, 167 L.Ed.2d 812 (2007).
[34] House Bill 369, *available at* https://www.flsenate.gov/Session/Bill/2019/369/BillText/er/PDF.
[35] Sober Home Task Force, Office of State Attorney Dave Aronberg, *available at* http://www.sa15.state.fl.us/stateattorney/SoberHomes/indexsh.htm.
[36] FLA. STAT. § 817.505, *available at* http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0800-0899/0817/Sections/0817.505.html.

[37] 42 U.S.C. § 1320a-7b, *available at* https://www.govinfo.gov/content/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7b.htm.
[38] *See* Florida Association of Recovery Residences, *available at* http://farronline.org/.
[39] "DCF Rebukes Florida Legislature on Community Housing Sober Living," SOBER LAW NEWS (Aug. 23, 2018), *available at* https://soberlawnews.com/dcf-rebukes-florida-legislature-on-community-housing-sober-living/.
[40] FLA. STAT. § 397.4873, *available at* http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0397/Sections/0397.4873.html.
[41] Chapter 83, Florida Statutes, *available at* http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0000-0099/0083/0083.html.
[42] FLA. STAT. § 435.07, Florida Statutes, *available at* http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0400-0499/0435/Sections/0435.07.html.
[43] *Id.* § 397.311(34) (2018), *available at* http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0300-0399/0397/Sections/0397.311.html.
[44] Hedegaard H., Miniño AM, Warner M., "Drug Overdose Deaths in the United States, 1999-2017," NCHS Data Brief, No. 329, Hyattsville, MD: National Center for Health Statistics, *available at* https://www.cdc.gov/nchs/products/databriefs/db329.htm.
[45] *See* Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007, which enhanced the protections of the MSP provisions and only required medical information to be reported with respect to Medicare beneficiaries who had coverage under group health plans as well as Medicare beneficiaries who received settlements, judgments or other payment from liability insurers, no-fault insurers or workers' compensation carriers.
[46] Group Health Plan (GHP) Reporting for Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients Communities Act, Frequently Asked Questions and Answers *Download available at* https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Group-Health-Plans/Whats-New/Whats-New.html (last visited June 21, 2019).
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[48] "A Strategic Look at Florida's Medical Tourism Opportunities," Florida Chamber Foundation, available at http://www.flchamber.com/wp-content/uploads/2016/06/Research_A-Strategic-Look-at-Floridas-Medical-Tourism-Opportunities.pdf.
[49] *See* CHS Press room and Media Releases, *available at* http://www.chs.net/investor-relations/press-room-media-releases/.