**March 2019**

Dear Health Law Section Members:

The Health Law Section (“HLS”) website has been updated with January through February 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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**ADMINISTRATIVE UPDATES**

**Department of Health has the Power to Suspend a Healthcare**

**Practitioner’s Occupational License for Defaulting on Student Loans**

Under Florida Law, the Department of Health (the “Department”) has the ability to suspend a healthcare practitioner’s occupational license for failing to repay a student loan issued or guaranteed by the state or the federal government.[[1]](#endnote-1) Furthermore, the Florida Legislature has instructed the Department that the healthcare practitioner’s license shall remain suspended “until new payment terms are agreed upon . . . , followed by probation for the duration of the student loan[.]”[[2]](#endnote-2) Moreover, a healthcare practitioner that is found to be violating this section will also incur a fine that is “equal to 10 percent of the defaulted loan amount.”[[3]](#endnote-3)

This issue was recently litigated in *Department of Health, Emergency Medical Oversight v. Litsch[[4]](#endnote-4)* when the Administrative Law Judge (“ALJ”) E. Gary Early was asked to decide whether the Respondent, a paramedic, violated section 456.072(1)(k), Florida Statutes, “*by failing to repay a student loan issued or guaranteed by the state or the federal government in accordance with the terms of the loan as alleged in the Administrative Complaint; and, if so, the appropriate penalty.*” In *Litsch*, the Department alleged that the Respondent had borrowed $17,500 in student loans, which he had failed to pay since 1997 despite having consolidated his loans in 2005. After consolidating his loans, the Respondent received a deferment for payments for 59 months and then received a forbearance from payment for 63 months. As such, his loan payment became due on October 21, 2015, but he failed to make the payment. The Florida Department of Education was the guarantor for the Respondent’s student loans, including the consolidated loan.[[5]](#endnote-5) On November 10, 2016, the Department of Education defaulted the Respondent on his student loans. This is because *“[a]n education loan default occurs when a borrower fails to make required payments on a loan for 270 days*.”[[6]](#endnote-6)

The evidence in the proceeding consisted mostly of documentary evidence of the student loan records; however, the ALJ also took a negative inference against the Respondent since the Respondent invoked his Fifth Amendment privilege and declined to respond to discovery requests or to testify in trial. The ALJ specifically noted that:

*“Given the competent and substantial documentary evidence establishing the existence and legitimacy of Respondent’s student loans, the only rational conclusion to be drawn from Respondent’s assertion of his Fifth Amendment privilege is that he is aware of his obligation to pay his student loans and has not done so.”*[[7]](#endnote-7)

After considering the facts in the case, the ALJ found that the Respondent had violated Section 456.072(1)(k), Florida Statutes, and recommended that the Respondent’s paramedic license be suspended until new loan payment terms were agreed upon, that the Respondent be placed on probation for the duration of the student loan repayment, that the Respondent pay a fine equal to 10 percent of the defaulted loan, and that the Respondent pay the costs related to the investigation and prosecution in this matter.[[8]](#endnote-8)

Based on the foregoing, Florida healthcare practitioners and their counsel must always keep in mind the potential impact on healthcare practitioners’ licenses and ability to practice in the event of default of student loan obligations.

**Submitted by: Angelina Gonzalez, Esq., *Panza Maurer & Maynard, P.A.***

**COMPLIANCE UPDATES**

**DOJ’s New Tool in Fighting Unlawful Dispensing of Opioids**

In a first-of-its-kind False Claims Act complaint, the U.S. Department of Justice (“DOJ”) filed an *ex parte* motion for a temporary restraining order (“TRO”), seeking injunctive relief as well as civil monetary penalties against two Tennessee pharmacies accused of unlawfully dispensing opioids resulting in patient overdoses and deaths.[[9]](#endnote-9)

The Court granted the TRO to temporarily close the defendants’ pharmacies without the need for advance notice to them. Consequently, the government may now bypass the lengthy and difficult administrative process for suspending or removing a pharmacy’s registration with the Drug Enforcement Administration by seeking a TRO against a pharmacy evidencing violations of the Controlled Substances Act.

The Complaint and TRO, filed on February 7, 2019, made allegations against two pharmacies, Oakley Pharmacy, Inc., doing business as Dale Hollow Pharmacy, and Xpress Pharmacy of Clay County, LLC, among others. The Complaint alleged that the pharmacies violated the Controlled Substances Act by (i) knowingly dispensing controlled substances without a valid prescription and (ii) knowingly and intentionally distributing and dispensing controlled substances outside the usual course of professional practice of pharmacy. The Complaint further alleged violations of the False Claims Act related to funds paid by Medicare for the dispensed medications. According to the Complaint, the pharmacies unlawfully dispensed opioid medications that were tied to the deaths of several individuals and the overdose treatment of at least 12 Medicare beneficiaries.

The *ex parte*restraining order in this case highlights the innovative tools the DOJ will use to combat the opioid crisis. This case also alerts pharmacies that, if they do not sufficiently monitor opioid prescriptions, the DOJ may seek to temporarily close them at the beginning of an investigation, prior to receiving notice or the opportunity to present a defense.

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

**Don’t Skip the Peer Review Process for Physicians under**

**an Exclusive Service Agreement.**

In a recent California case, *Economy v. Sutter East Bay Hospitals*, the California Court of Appeals held that a hospital cannot avoid its obligation to provide notice and a hearing before terminating a doctor’s ability to practice in the hospital by directing the medical group employing the doctor to refuse to assign the doctor to the hospital.[[10]](#endnote-10)

As part of an anesthesiology group’s exclusive contract with Sutter East Bay Hospital, the anesthesia group agreed to remove any physician from the schedule who jeopardized the quality of patient care provided at the hospital. After repeatedly discovering quality concerns regarding an anesthesiologist’s care, the hospital instructed the anesthesia group to stop scheduling the anesthesiologist at its hospital. The group asked the anesthesiologist to resign and when he refused, it terminated him.

The anesthesiologist, Dr. Kenneth Economy, sued the hospital for violating his right to a peer review hearing. The hospital argued that it had not taken any action that would trigger the right to a hearing. The court disagreed holding that the hospital’s request to remove Dr. Economy from the schedule was the equivalent of a medical disciplinary reason and constituted a summary suspension. Dr. Economy was awarded $3.8 million in damages.

Although this case was decided under California law, Florida law also requires hospitals to provide a fair review of the issues before initiating physician discipline. It is unclear if this court’s interpretation of what constitutes disciplinary action will be adopted by other jurisdictions, but Florida hospitals and their medical staffs should consider this ruling before asking an employer to take action against an employed provider in lieu of starting the medical staff disciplinary process.

**Submitted by: Patricia Calhoun, Esq., *Carlton Fields***

**LEGISLATIVE UPDATES**

**Florida Constitutional Amendment V, Section 21 –**

**Game Changer for Administrative Law**

Businesses regulated by Florida agencies and lawyers who practice in the area of administrative law need to be aware of the adoption and implications of Amendment V, Section 21 to the Florida Constitution, which was approved by the Florida voters in November 2018. The amendment reads:

*Judicial Interpretation of Statutes and Rules.*

*In interpreting a state statute or rule, a state court or an officer hearing an administrative action pursuant to general law may not defer to an administrative agency’s interpretation of such statute or rule, and must instead interpret such statute or rule de novo.*

This amendment is changing administrative law. Florida courts have historically followed the Chevron Deference policy articulated in the landmark case *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 468 U.S. 837 (1984). Here, the Court discussed the concept that judicial deference should be given to agencies charged with regulating businesses governed by statutes and rules within the agencies domain. Until now, practicing Florida lawyers knew that an agency’s own interpretation of statutes and rules would be given significant weight in administrative hearings and in courts of law. Amendment V, Section 21 changes this by constitutionally prohibiting judges and officers hearing administrative actions from deferring to an agency’s interpretation of statutes and agency rules. A judge or administrative officer could interpret a rule or statute the same way advocated by an agency but they must take a fresh look de novo.

On February 5, 2019, the First District Court of Appeals (“1st DCA”) issued an order requiring an administrative agency to issue a permit to a company that wanted to drill in the Florida Everglades. The circuit court had upheld the hearing officer’s decision to deny the permit but the 1st DCA overruled it, citing the new de novo review of statutes and rules required by Amendment V, Section 21.[[11]](#endnote-11)

On February 27, 2019, the 1st DCA issued three decisions overruling Division of Administrative Hearings hearing officers and circuit court affirmations that the Agency for Health Care Administration was entitled to an “overpayment” based upon a retrospective application of a statute. In each of the decisions, the 1st DCA cited the application of the new Amendment V, Section 21, prohibiting courts from giving deference to agency interpretations.[[12]](#endnote-12)

Health lawyers should take note and follow these cases and cases to come. The effect of Amendment V, Section 21 on administrative rulings will be enormous. It has broad significance with regard to less than clear statutes and rules. It could decrease the authority of agencies that are the most familiar with businesses and the industries they regulate and could potentially be used by businesses that see gray areas of the law as opportunities now worth challenging. Lawyers will be asked by clients to gauge the likelihood of success at the conclusion of court proceedings and Amendment V, Section 21’s effect will have to be taken into consideration and to measure that against the anticipated legal costs associated with an action. Agencies with increased scrutiny on budget expenditures also will have to consider litigation costs and likelihood of prevailing in light of Amendment V, Section 21. It also may result in additional legislative action if the legislature is not in agreement with the manner in which a particular court or courts are interpreting laws they enacted.

**Submitted by: Jeanne E. Helton, Esq., *Smith Hulsey & Busey***

**Florida’s House proposes adding a significant financial “carrot” to encourage reimbursement of telehealth use by health care providers and expand health access and options to its residents**

Florida may be joining the race toward improving health care access for its residents via telehealth. Members of Florida’s House Health Quality Subcommittee approved the telehealth-friendly bill ([HB 23](http://static-lobbytools.s3.amazonaws.com/bills/2019/pdf/0023.pdf)), which if passed, would create a substantial tax-incentive for health plans and HMOs to cover and reimburse providers for telehealth services. According to the [Fall 2018 Reimbursement Policies report](https://www.cchpca.org/telehealth-policy/state-telehealth-laws-and-reimbursement-policies-report) by the Center for Connected Health Policy, Florida lags behind 39 states and the District of Columbia when it comes to private payer telehealth parity laws, with Kansas, Iowa, and Utah joining the ranks when their private payer parity laws went into effect at the beginning of this year.

If passed, HB 23 would:

* Encourage coverage and reimbursement for telehealth services. Effective January 1, 2020, “any health insurer and health maintenance organization [(HMO)] that cover services provided by telehealth” would receive a tax credit, which would rollover up to five years if not fully used in any single year. The insurers and HMOs would be allowed a tax credit equal to 0.001 percent of total insurance premiums received on accident and health insurance policies or plans delivered or issued in Florida in the previous calendar year that provide medical, major medical, or similar comprehensive coverage.
* Define “Telehealth”. Telehealth would mean “the use of synchronous or asynchronous telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, patient assessment, diagnosis, consultation, treatment, and monitoring; transfer of medical data, patient and professional health-related education; public health services; and health administration.” It would exclude “audio-only telephone calls, e-mail messages, or facsimile transmissions.”
* Incorporate an expansive list of healthcare providers covered under the tax incentive. Florida would explicitly recognize the following types of licensed or certified healthcare providers to provide their services via telehealth platforms:
	+ Behavior analysts;
	+ Medical transportation services (under Part III of Chapter 401 of the Florida statutes);
	+ Acupuncturists;
	+ Physicians;
	+ Osteopathic physicians;
	+ Chiropractors;
	+ Podiatrists;
	+ Optometrists;
	+ Nurses and Nursing Assistants;
	+ Pharmacists;
	+ Dentists, Dental Hygienists, and Dental Laboratories;
	+ Midwives;
	+ Speech-Language Pathologists and Audiologists;
	+ Occupational Therapists;
	+ Radiologists;
	+ Respiratory Therapists;
	+ Dieticians and Nutritionists;
	+ Athletic Trainers;
	+ Orthotists, Pedorthists, and Prosthetists;
	+ Electrologists;
	+ Massage Therapists;
	+ Medical Physicists;
	+ Opticians and Hearing aid specialists;
	+ Physical Therapists;
	+ Psychologists; and
	+ Clinical Social Workers, Marriage and Family Therapists, Mental Health Counselors, and Psychotherapists.
* Allow out-of-state healthcare providers to provide services without a Florida license. Out-of-state providers would be able to register with the applicable board to provide telehealth services to Florida residents. This would allow out-of-state healthcare providers, with valid licenses and/or certifications, and in good standing in their own respective states, to provide telehealth services to Florida residents without having to first obtain a Florida license and/or certification, which is currently required. Presumably, out-of-state health providers would also be covered in the tax incentive, should insurers and HMOs cover and reimburse telehealth services performed by those providers.

Although the bill provides incentives to promote telehealth access, the bill does not require that insurers and HMOs reimburse for telehealth services. Although several progressive, value-based insurers in Florida have openly advocated for telehealth expansion or included certain telehealth services in their offerings, this is a nascent trend. Many telehealth providers and proponents of telehealth have discovered that without statutory mandates, most insurers are hesitant about covering and reimbursing telehealth services. If the House bill passes into law, it will be interesting to see whether the tax incentive carrots will be as effective as mandates in promoting telehealth use across providers and plan enrollees.

**Submitted by: Daniel Kim, Esq., and Kathleen Premo, Esq.,**

 ***Epstein Becker & Green, P.C.***

**Florida’s Medicaid Expansion Debate:**

**Cost Considerations and Implications for the Uninsured**

One of the more significant events of 2018, was Florida’s continued rejection of the call for Medicaid expansion under the Affordable Care Act - a/k/a “Obamacare.” Florida remains one of 17 states that have not expanded Medicaid. The State’s position is likely to remain unchanged in 2019 given the political realities of the Governor’s office and both legislative chambers. This comes despite a significant increase in the number of uninsured individuals and a projected loss over the next 10 years to Florida of approximately $65 billion dollars.[[13]](#endnote-13) A recent study by the non-partisan Urban Institute found that an expansion of Medicaid in Florida would cover an additional 650,000 lives and lower the State’s uninsured rate from 15.7% to nearly 11%.[[14]](#endnote-14) Further, while many of the State’s most influential businessmen and decision makers have indicated support for the expansion of Medicaid,[[15]](#endnote-15) Florida Republican leadership were more focused in 2018 on adopting alternative measures such as block grants, market-based reforms, and premium assistance.

The reasons often cited for resistance to Medicaid expansion are varied. Republican lawmakers in the State have argued that Florida simply cannot afford to expand this costly program, and that the promises of continued federal funding, currently at 90% of realized costs, cannot be relied upon. House Speaker, Jose Oliva, has gone on record as stating: “The only thing expanding Medicaid would do, is to create further pressure on a system created as a safety net to help low-income people and to subsidize some elderly care. It was not designed to do what people are trying to get it to do.”[[16]](#endnote-16) While Florida’s Democratic leaders argue for such expansion, its Republican leaders remain firmly committed against it. Because of this, despite what appears to be growing public support, Medicaid expansion in Florida seems unlikely in coming years absent a significant change of position by Florida’s lawmakers.

**Submitted by: Steven A. Grigas, Esq., *Akerman LLP***

**Recent CMS Announcement Sunsets Home Health Agency Provider Enrollment Moratoria, but the Industry Should Act Quickly to Enroll or Expand**

The Centers for Medicare and Medicaid Services (“CMS”) recently [announced](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/ProviderEnrollmentMoratorium.html) an end to its long-standing home health agency (“HHA”) provider enrollment moratoria effective January 30, 2019. This is undoubtedly welcome news to the HHA industry in Florida, however uncertainty remains with regard to the finality of this agency action and whether any moratoria are likely to be reimposed in the near term. As a result, HHA providers desiring growth should take action soon to initiate a new enrollment or expand an HHA’s footprint in a state through enrollment of a branch location.

In 2013, CMS imposed temporary moratoria on newly enrolling Medicare HHA providers in select geographic regions in Florida, Illinois, Michigan, and Texas due to the significant potential for fraud, waste, and abuse in those particular geographic regions.[[17]](#endnote-17) Not only did the moratoria prevent new HHA Medicare enrollment, but it also limited the ability of existing enrolled HHAs to expand, because the addition of sub-units and branches under an existing HHA’s Medicare provider number was subject to the moratoria to the same extent as a newly enrolling HHA.[[18]](#endnote-18) CMS continuously extended the moratoria in six-month increments through 2018, and ultimately expanded geographic reach of the moratoria to prohibit enrollment or expansion of HHAs statewide in Florida, Illinois, Michigan, and Texas.[[19]](#endnote-19) In each of the notices announcing the HHA moratorium extension, CMS explained that it consulted with HHS-OIG and determined the significant potential for fraud, waste, and abuse continued to exist regarding HHAs in these particular geographic areas. CMS stated that it needed to renew each moratoria so that it could continue with administrative actions to combat fraud and abuse, such as payment suspension and revocations of provider numbers, because providers might otherwise avoid sanctions, recoupment efforts or other debt obligations owed to the Medicare program by simply re-enrolling in Medicare through a new business entity.[[20]](#endnote-20)

*Implications of CMS Announcement Ending Moratorium*

CMS announced the end of the moratoria through a very short statement on its website stating only that, “there are no active Medicare Provider Enrollment Moratoria in any State or U.S. territories.” CMS effectively allowed the HHA enrollment moratoria to expire. It is noteworthy that CMS did not publish a formal notice in the Federal Register announcing the expiration of the HHA moratoria given that pursuant to 42 C.F.R. § 424.570(d), CMS is supposed to publish a document in the Federal Register when it lifts a moratorium and CMS had published each of its moratoria extensions in the Federal Register. CMS also did not provide any explanation as to why it decided against extending the moratoria. The brief announcement did not identify whether CMS and HHS-OIG have seen a reduction in the significant fraud and abuse risks posed by new HHA enrollment in Florida, Illinois, Michigan, and Texas, or whether there is another rationale why CMS believes the moratoria is no longer needed. Through feedback sought by the National Association for Home Care & Hospice, CMS explained that the moratoria were intended to be a temporary tool, and that additional and new safeguards that have been implemented since the moratoria were initially imposed will continue the work to protect Medicare resources from fraud, waste and abuse. This feedback suggests that CMS has no immediate plans to reinstate any moratoria. However, the lack of formal publication lifting the moratoria, coupled with no official explanation for its lifting, leaves the HHA industry with uncertainty regarding the permanence of this announcement and whether CMS is likely to take additional action to re-initiate the moratoria again at any time.

Providers that want to expand their HHA footprint in Florida would be wise to move quickly to submit their enrollment applications into their Medicare Administrative Contractor (“MAC”). If CMS decides to re-initiate a temporary moratorium in any of these states, providers who have submitted enrollment applications to CMS and received approval by Medicare contractors, but have not yet entered PECOS, will be exempt from the moratorium.[[21]](#endnote-21)

HHAs have two options for expanding their Medicare business: 1) submit an initial enrollment application for a parent HHA; or 2) submit a change of information application for a branch associated with a parent HHA. Obtaining Medicare certification for a parent HHA is more burdensome than applying for a branch, as it requires an initial enrollment application. The Medicare enrollment process for HHAs is more involved than some other provider types because CMS has imposed special enrollment requirements on HHAs such as capitalization requirements. Accordingly, the time it takes to process and approve an initial HHA application can be lengthy. In addition, CMS also recently announced it would place some newly enrolled HHAs into a provisional period of enhanced oversight effective February 15, 2019.[[22]](#endnote-22) The provisional period will include a suppression of all Request for Anticipated Payment (“RAP”) payments for 30 days to one year. Existing providers may instead want to add a branch location to an existing enrollment. A branch is a location that services patients in the same geographic area as the parent, but the HHA must meet certain proximity and integration requirements in order to demonstrate that it shares administration with the parent on a daily basis. Branches do not need to enroll separately, thus allowing CMS to process and approve the application faster than an initial enrollment application.

The question of whether a particular location qualifies as a branch requires careful consideration. Providers must also consider whether it is best from an operational and billing standpoint for locations to bill separately or together with the parent HHA. Importantly for both enrollment options, prior to initiating Medicare enrollment the provider must have a valid lease for the location in place and ensure that the HHA has an active state license to operate.

CMS’ announcement ending the moratoria creates a significant opportunity to expand a home health provider’s footprint in several states with high Medicare enrollee populations, but is not without potential risks. Providers should both act quickly to take advantage of this new regulatory landscape before CMS imposes another moratorium but also act carefully to submit an enrollment application that meets all of the Medicare requirements. This may be a one-time opportunity so it is important to submit a comprehensive, accurate, and operationally feasible application. Application errors or errors in regulatory interpretations will result in delays in processing, create a survey risk, and impede Medicare approval. Furthermore, while pending applications may be processed if the moratoria is resurrected, this only applies to perfect applications submitted before the imposition of a moratorium. Incomplete or inaccurate applications will not be grandfathered in. Finally, as the application requires an executed lease, we also recommend obtaining legal guidance with a sophisticated approach to lease contracting in the event the HHA cannot obtain regulatory approval to enroll in Medicare.

**Submitted by: Emily Bajcsi, Esq., Francesca Ozinal, Esq., and Kathleen Premo, Esq,**

 ***Epstein Becker & Green, P.C.***

**The SUPPORT for Patients and Communities Act &**

**Impact of Eliminating Kickbacks in Recovery Act of 2018**

Data from the Centers for Disease Control and Prevention demonstrates that the number of drug overdose deaths in the United States surpassed 72,000 in 2017.[[23]](#endnote-23) To address the nation’s growing opioid crisis and reduce overdose deaths, the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (the “SUPPORT Act”) was enacted on October 24, 2018.

The 660-page SUPPORT Act is a compilation of dozens of bills submitted by legislators. The bipartisan legislative package takes a multifaceted approach to tackle opioid misuse including expanding access to effective treatment for opioid use disorder (“OUD”), promoting the development of alternative treatments for pain management, and coordinating care and facilitating access to treatment based on patients’ unique needs.

Notable provisions in the SUPPORT Act include:

* Medicare coverage of medication-assisted treatment (“MAT”), including all FDA-approved drugs (e.g., methadone), counseling services, and behavioral therapy, from October 2020 through September 2025, unless a state opts out due to provider shortages.
* Required guidance from the Centers for Medicare and Medicaid Services (“CMS”) on prescribing opioids to Medicare patients.
* Permanent allowance of nurse practitioners and physician assistants to prescribe buprenorphine, an anti-addiction medication. Nurse anesthetists, nurse midwives and clinical nurse specialists may now prescribe buprenorphine for the next five years.
* Expanded access to MAT by increasing the number of patients with OUD qualified providers can treat with buprenorphine in the first year.
* Expanded limit of patients that qualified physicians can treat with buprenorphine at any one time to 275, up from the current limit of 100 patients.
* Research funding for the development of new non-addictive painkillers, non-opioid drugs and treatments.

The legislative package includes several provisions that support and expand telemedicine programs aimed at combatting the opioid crisis. Medicare limits coverage for telemedicine services to beneficiaries who reside in geographically rural areas and who seek telemedicine services at designated originating sites (e.g., physician’s office, rural health clinic).[[24]](#endnote-24)  Section 2001 of the SUPPORT Act eliminates these restrictions. Beginning July 1, 2019, Medicare coverage will include telemedicine services furnished to beneficiaries with substance use disorders wherever they receive services. Additionally, CMS is required by Section 1009 of the SUPPORT Act to issue Medicaid guidance on the treatment of substance use disorders through telemedicine services.

All-Payor Anti-Kickback Prohibition - Eliminating Kickbacks in Recovery Act of 2018

Section 8122 of the SUPPORT Act, known as the Eliminating Kickbacks in Recovery Act of 2018 ("EKRA"), codified at 18 U.S.C. § 220, establishes an all-payor anti-kickback prohibition with severe criminal penalties for taking or paying a kickback (or any remuneration) for referrals to recovery homes, clinical treatment facilities, and clinical laboratories.[[25]](#endnote-25)  Specifically, EKRA makes it illegal to knowingly and willfully (1) solicit or receive remuneration for referring a patient to a “recovery home, clinical treatment facility, or laboratory” or (2) pay or offer remuneration to either “induce a referral of an individual to” or “in exchange for an individual using the services of” a “recovery home, clinical treatment facility, or laboratory.”[[26]](#endnote-26)

The intent of EKRA was to address patient brokering, a common practice by recovery homes and treatment facilities of engaging third parties to recruit patients in exchange for kickbacks.[[27]](#endnote-27) However, the express wording of the statute applies to any referral made to a recovery home, clinical treatment facility, or laboratory, regardless if the referral is opioid-related, and thus has a sweeping impact.[[28]](#endnote-28)

Additionally, EKRA does not replace or amend the Federal AntiKickback Statute, 42 U.S.C. 1320-7b(b) ("AKS"), or protect any conduct already permitted by it. While EKRA has many similarities to the AKS, it contains a number of noteworthy differences from prior federal prohibitions on kickbacks.

First, EKRA defines “laboratory” to include any CLIA-certified laboratory and “health care benefit program” to mean “any public or private plan or contract . . . under which any medical benefit, item, or service is provided to any individual.”[[29]](#endnote-29)   By expanding the kickback prohibition to private payors, EKRA covers a much broader spectrum of relationships and referrals compared to the AKS. Specifically, EKRA applies to all laboratories that conduct business with a health care benefit program.

Second, EKRA contains only eight (8) statutory exceptions.[[30]](#endnote-30)  To put that in perspective, the AKS has thirty-seven (37) statutory and regulatory safe harbors. Fundamental AKS safe harbors have no correlate exception to EKRA – resulting in many commonplace arrangements being subject to potential liability.  One fundamental difference between the EKRA statutory exceptions and the AKS safe harbors is the absence of the AKS’ bona fide employee safe harbor.

EKRA prohibits payments to employees and independent contractors if the payments were determined or varied by: (1) the number of individuals referred; (2) the number of tests or procedures performed; or (3) the amount billed to or received from a patient’s insurance plan.[[31]](#endnote-31) Under the AKS bona fide employee safe harbor, clinical laboratories and other health care organizations are permitted to pay incentive-based compensation to sales personnel based on revenues generated from their marketing activities.[[32]](#endnote-32)

Because of the protections offered by the AKS bona fide employee safe harbor, properly structured incentive-based compensation arrangements are commonly utilized by clinical laboratories and other health care organizations. Now, such incentive-based compensation arrangements are problematic and risk violating EKRA.

There is a disconnect between Congress’ intent in passing the SUPPORT Act (addressing opioid recovery and treatment) and the wide scope and impact of EKRA’s operative language. Governmental guidance will be necessary to determine the breadth of EKRA's prohibition on incentive-based compensation and its interplay with permissible arrangements under the AKS.  Accordingly, until such governmental guidance is published, recovery homes, clinical treatment facilities, and clinical laboratories will need to reevaluate and reassess their relationships related to all incentive-based compensation arrangements involving sales personnel.

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

**PUBLIC HEALTH UPDATES**

**FDA To Mandate Action under SUPPORT for Patients and Communities Act;**

**Calls for Opioid Effectiveness Studies**

In another regulatory attempt to address public health outcomes vis-à-vis opioids, the Food and Drug Administration (“FDA”) Commissioner Scott Gottlieb recently announced FDA's intent to require drug companies to study the efficacy of prescription opioids to treat chronic pain. This is in addition to FDA's work as announced earlier this year ["to stop the spread of illicit opioids, further secure the U.S. drug supply chain and forcefully confront opioid epidemic."](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631195.htm)

FDA gained this authority under the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act.[[33]](#endnote-33) [FDA has interpreted this law](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624268.htm) to provide "new authority that will help [FDA] advance [its] understanding of opioid pain medicines by clarifying the FDA’s authority to require post-market studies on the efficacy of drugs over time under certain circumstances."

[The Commissioner has explained](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm624268.htm) that "[f]or example, despite the prevalence of opioid analgesics use to treat chronic pain, there are limited data on the long-term efficacy of opioid analgesics, and whether the long-term use increases the likelihood of addiction, as well as the overall place of opioids in the long-term treatment of pain. More research is needed to fully understand this question."

FDA will require opioid manufacturers to sponsor research of its opioid products in an unbiased, controlled environment to examine the long-term efficacy of opioid analgesics, likely to compare that efficacy with the risk of addiction, in order to inform potential continued rulemaking regarding their labeling, prescribing, dispensing, and use. FDA will also require the study of the relationship between opioids and hyperalgesia (an increased sensitivity to pain), likely in the face of ongoing debate regarding whether opioids alter pain sensations.[[34]](#endnote-34)

FDA has focused on opioid regulation increasingly as public discourse and attention has focused on the proliferation of opioid use and dependence. FDA's published timeline of its involvement is available [here](https://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM566985.pdf).

**Submitted by: Jarred L. Reiling, Esq., *Akerman LLP***

**PRIVACY UPDATES**

**Clamping Down on Cybersecurity**

It is no secret that health insurers maintain large amounts of consumer information and for that reason are primary targets of cyberattacks. And while the cyberattacks take on various forms such as email phishing and ransomware, the outcome is always the same – the Personally Identifiable Information and Personal Health Information (“PHI”) of individual consumers are placed at risk and health insurers are exposed to various types of liability including but not limited to monetary penalties, fines, and enforcement actions. The cyberattack that Anthem faced in 2015, for example, resulted in the exposure of electronic PHI of nearly 79 million individuals and a $16 million settlement to the U.S. Department of Health and Human Services Office for Civil Rights (“OCR”) for potential violations of the Health Insurance Portability and Accountability Act (“HIPAA”).[[35]](#endnote-35) Unfortunately, cyberattacks have become the most prevalent type of reported data breach in the past few years. In fact, as of February 27, 2019, almost half of the data breaches reported to OCR within the last 24 months were listed as a “Hacking/IT Incident.”[[36]](#endnote-36) To combat the surge in cyberattacks, the insurance industry will continue to see an increase in legislative and regulatory activity concerning cybersecurity.

1. **New York Sets Trend on Cybersecurity Measures**

The first state to establish robust cybersecurity requirements for covered entities was New York. Under the cybersecurity regulation, which became effective March 1, 2017, a “covered entity” means “any Person operating under or required to operate under a license, registration…or similar authorization under the Banking Law, the Insurance Law or the Financial Services Law.”[[37]](#endnote-37)  In other words, health insurance companies, agents and any other person or entity licensed under New York Insurance law are required to comply with the New York cybersecurity regulation found at 23 NYCRR Part 500. Thus, if a Florida domiciled health insurer or any other non-New York domiciled entity holds a certificate of authority or license subject to New York insurance laws, that non-New York domiciled insurer must comply with the New York cybersecurity regulation. There are limited exemptions under the regulation including but not limited to the following: (1) covered entities with fewer than 10 employees in New York; (2) covered entities with less than $5 million in gross annual revenue of the last three fiscal years from New York business operations; and (3) covered entities with less than $10 million in year-end total assets.[[38]](#endnote-38) Such covered entities are only required to comply with certain provisions of the regulation.[[39]](#endnote-39) However, generally, covered entities must:

* Maintain a cybersecurity program and written policies & procedures (“P&Ps”)
* Designate a Chief Information Security Officer to oversee the cybersecurity program and report at least annually to the board
* Monitor and test the cybersecurity program
* Maintain audit trails
* Limit Access Privileges
* Conduct Periodic Risk Assessments
* Implement written P&Ps for Third Party Service Providers
* Require multi-factor authentication
* Include P&Ps for secure disposal of Non-Public Information
* Train staff on cybersecurity
* Require encryption of nonpublic information
* Establish an incident response plan
* Notify the superintendent within 72 hours of a cybersecurity event
* Certify Compliance with the regulation annually[[40]](#endnote-40)

While penalties for non-compliance are not explicitly outlined in the regulation, one can reasonably conclude that non-compliance may lead to monetary penalties.

1. **National Association of Insurance Commissioners (“NAIC”) Adopt Model Law**

In October 2017, months after New York adopted its cybersecurity regulation, the NAIC adopted the Insurance Data Security Model Law (“Model Law”). Like New York’s cybersecurity regulation, the Model Law requires implementation and maintenance of an information security program to safeguard nonpublic information, and establishes industry standards for the investigation and notification of a cybersecurity event. One of the key similarities between the New York regulation and the Model Law is that both broadly define “nonpublic information” to include personal information and business related information.[[41]](#endnote-41) The Model Law also requires oversight of third party vendors, a written incident response plan, and an annual certification of compliance. Unlike New York’s cybersecurity regulations, however, the Model Law provides specific notification requirements to ceding insurers, places the onus for oversight of the information security program on the board of directors or a designated committee, and requires an insurer to implement security measures and controls based on its own risk assessment.

To date, South Carolina, Ohio and Michigan are the only states that have adopted the Model Law in whole or in part.[[42]](#endnote-42) The main differences between the Model Law and the states’ requirements are around breach notification requirements for licensees reporting to regulators (South Carolina requires notification within 72 hours; Ohio requires notification within 3 business days; and Michigan requires notification within 10 business days).

1. **Future of NAIC Model Law**

It is likely that Florida and other states will adopt the Model Law in the near future. Regardless, a Florida-domiciled licensee including an insurer, broker, or agency that does business in any of the states that have adopted the Model Law may be required to comply with the various states’ cybersecurity requirements including reporting if the cybersecurity event impacts 250 or more consumers residing in MI, NY or OH.

Moreover, if an entity’s home state is like Ohio, licensees may have as little as 12 months from the date a cybersecurity law is enacted to implement a cybersecurity program. For that reason, Practitioners should encourage their clients to proactively build a comprehensive cybersecurity program now.

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1. *See* Fla. Stat. § 456.072(1)(k). [↑](#endnote-ref-1)
2. *Id.* [↑](#endnote-ref-2)
3. *Id.* [↑](#endnote-ref-3)
4. *Department of Health, Emergency Medical Oversight v. Litsch* Case No. 18-2891PL at \*1-2 (Fla. Div. of Admin. Hearing, Sept. 12, 2018) [↑](#endnote-ref-4)
5. *Id.* at 9. [↑](#endnote-ref-5)
6. *Id.* [↑](#endnote-ref-6)
7. *Id.* at 16 [↑](#endnote-ref-7)
8. *Id.* at 18. [↑](#endnote-ref-8)
9. *U.S. v. Oakley Pharmacy, Inc.*, Case No. 2:19-cv-0009 (M.D. Tenn. Feb. 7, 2019). You can access a copy of the DOJ’s memorandum in support of the TRO at http://www.fdalawblog.net/wp-content/uploads/2019/02/US-v-Oakley-Pharmacy-Memo-Supporting-Ex-Parte-Motion-00517204.pdf. [↑](#endnote-ref-9)
10. *Economy v. Sutter East Bay Hospitals*, Case No. A150211 (Cal. Ct. App. Feb 4, 2019). You can access a copy of the decision at <http://www.courts.ca.gov/opinions/documents/A150211.pdf>. [↑](#endnote-ref-10)
11. *See* *Kanter Real Estate LLC vs. Department of Environmental Protection, City of Miramar and Broward County*, 2019 WL 436613, *available at* <https://www.1stdca.org>. [↑](#endnote-ref-11)
12. *See* *Lee Memorial Health System v. State of Florida Agency for Health Care Administration* and a companion case, *Cape Memorial Hospital, Inc. v. State of Florida Agency for Health Care Administration*, *available at* <https://www1stdca.org>. [↑](#endnote-ref-12)
13. Louise Norris, *Florida and the ACA’s Medicaid Expansion*, healthinsurance.org (Aug. 28, 2018), <https://www.healthinsurance.org/florida-medicaid/>. [↑](#endnote-ref-13)
14. Matthew Buettgens, *The Implications of Medicaid Expansion in the Remaining States: 2018 Update*, Urban Institute (May 17, 2018), <https://www.urban.org/research/publication/implications-medicaid-expansion-remaining-states-2018-update>. [↑](#endnote-ref-14)
15. Adam Wollner, *Florida Influencers: Medicaid Expansion Should be Top Health Care Priority for Tallahassee*, Miami Herald (Aug. 27, 2018), [https://www.miamiherald.com/news/politics-government/influencers /article217265870.html](https://www.miamiherald.com/news/politics-government/influencers%20/article217265870.html). [↑](#endnote-ref-15)
16. Phil Galewitz and David Smiley, *In Florida, Mid –Term Elections Hold Little Hope for Medicaid Expansion*, Miami Herald (July 6, 2018), <https://www.miamiherald.com/news/health-care/article214432969.html>. [↑](#endnote-ref-16)
17. 78 Fed. Reg. 46339 (July 31, 2013). [↑](#endnote-ref-17)
18. CMS has since phased out subunits. *See* <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-03.pdf>. [↑](#endnote-ref-18)
19. 82 Fed. Reg. 2363 (Jan. 9, 2017), 82 Fed. Reg. 35122 (July 28, 2017), 83 Fed. Reg. 01783 (Jan. 29, 2018), and 83 Fed. Reg. 42037 (Aug. 20, 2018). [↑](#endnote-ref-19)
20. 82 Fed. Reg. 2363 (Jan. 9, 2017). [↑](#endnote-ref-20)
21. 42 C.F.R. § 424.570(a)(iv). [↑](#endnote-ref-21)
22. *See* MLN SE19005, *What New Home Health Agencies (HHAs) Need to Know About Being Placed in a Provisional Period of Enhanced Oversight*, CMS (Feb. 15, 2019), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19005.pdf>. [↑](#endnote-ref-22)
23. *See* Margot Sanger-Katz, *Bleak New Estimates in Drug Epidemic: A Record 72,000 Overdose Deaths in 2017*, N.Y. Times (Aug. 15, 2018), <http://www.nytimes.com/2018/08/15/upshot/opioids-overdose-deaths-rising-fentanyl.html>. [↑](#endnote-ref-23)
24. 42 U.S.C. § 1395m(m)(4)(c)(i). [↑](#endnote-ref-24)
25. 18 U.S.C. § 220(a). [↑](#endnote-ref-25)
26. *Id.* [↑](#endnote-ref-26)
27. *See* 164 Cong. Rec. H9244, H9247, H9253 (daily ed. Sept. 28, 2018), available at <https://www.gpo.gov/fdsys/pkg/CREC-2018-09-28/pdf/CREC-2018-09-28.pdf>. [↑](#endnote-ref-27)
28. 18 U.S.C. §§ 220(a), (e). [↑](#endnote-ref-28)
29. 42 U.S.C. 263a(a); 18 U.S.C. § 24(b). [↑](#endnote-ref-29)
30. 18 U.S.C. § 220(b). [↑](#endnote-ref-30)
31. *Id.* § 220(b)(2). [↑](#endnote-ref-31)
32. 42 C.F.R. § 1001.952(i). [↑](#endnote-ref-32)
33. *See, e.g.*, 21 U.S.C. § 355-1(b)(1)(E) ("any failure of expected pharmacological action of the drug, which may include reduced effectiveness under the conditions of use prescribed in the labeling of such drug, but which may not include reduced effectiveness that is in accordance with such labeling.") (emphasis added). See also Pub. L. No. 115-271, 132 Stat. 3940, § 3041(a) (amending "Definition of Adverse Drug Experience"). [↑](#endnote-ref-33)
34. *See* K. Bannister & A.H. Dickenson, Opioid hyperalgesia, 4 Curr. Opin. Support Palliat. Care 1-5 (2010), *available at* <https://insights.ovid.com/pubmed?pmid=20019618> (last accessed Feb. 26, 2019). [↑](#endnote-ref-34)
35. *Anthem Pays OCR $16 Million in Record HIPAA Settlement Following Largest U.S. Health Data Breach in History*, HHS.gov (Oct. 15, 2018) <https://www.hhs.gov/about/news/2018/10/15/anthem-pays-ocr-16-million-record-hipaa-settlement-following-largest-health-data-breach-history.html> (last visited Feb. 27, 2019). [↑](#endnote-ref-35)
36. [*Cases Currently Under Investigation*, U.S. Department of Health and Human Services OCR https://ocrportal.hhs.gov/ocr/breach/breach\_report.jsf](https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf) (last visited Feb. 27, 2019) (210 of 430 cases reported from 3/2/2017 to 2/21/2019 pursuant to Section 13402(e)(4) of were as Hacking/IT Incidents). [↑](#endnote-ref-36)
37. N.Y. Comp. Codes R. & Regs. tit. 23,§ 500.01(c) [↑](#endnote-ref-37)
38. *Id.* § 500.19 [↑](#endnote-ref-38)
39. *Id.* [↑](#endnote-ref-39)
40. *Id.* §§ 500.02 - 500.17. [↑](#endnote-ref-40)
41. *See* NAIC Insurance Data Security Model Law, Section 3. [↑](#endnote-ref-41)
42. *See* S.C. Code Ann. §§ 38-99-10 to 38-99-100 (South Carolina); Ohio Rev. Code Ann. § 3965; Mich. Comp. Laws Serv. § 500.550 (Michigan) (all three states have enacted laws in 2018). [↑](#endnote-ref-42)