November 2019

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with September through October 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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Thank you,

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FRAUD & ABUSE UPDATES

Massive Healthcare Fraud and Abuse Enforcement Action Results in Charges Against 67 Individuals in Florida and Georgia.

On Wednesday, September 25, 2019, the Department of Justice ("DOJ") announced a massive joint enforcement action between federal and state authorities against 67 individuals in Florida and Georgia for their alleged involvement in a series of schemes for unnecessary medical services and illicit kickbacks that resulted in more than $160 million in fraudulent billings to Medicare, Medicaid, Tricare, ChampVA and several private insurance companies. In addition, after an investigation by Florida's Medicaid Fraud Control Unit ("MFCU"), a total of 16 of the Florida defendants were also charged with defrauding Medicaid out of more than $1.2 million. The unnecessary medical services ranged from home health and prescription drugs to durable medical equipment.

The full press release from the DOJ is available at https://www.justice.gov/opa/pr/florida-and-georgia-health-care-fraud-law-enforcement-action-results-charges-against-67.

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

Owner of Tampa-based Medical Marketing Company Sentenced to Prison for DNA Testing Fraud and Kickback Scheme

On October 4, 2019, the owner of a Tampa-based medical marketing company was sentenced to 70 months in prison for his role in a $2.2 million scheme that involved the payment of kickbacks to fraudulent medical clinics in Miami in exchange for referrals of Medicare beneficiaries whom were prescribed unnecessary and expensive genetic tests. Under this scheme, the clinics would attract beneficiaries by providing food and other inducements, and would then collect DNA samples of the beneficiaries and send them for unnecessary genetic testing. To make things worse, the results of the genetic testing were never provided to the beneficiaries. The defendant had been previously convicted in December 2015 of various healthcare fraud and abuse, money laundering and identity theft charges, and is currently serving a 14-year sentence on those charges.

The full press release from the DOJ is available at https://www.justice.gov/opa/pr/owner-tampa-area-medical-marketing-company-sentenced-prison-dna-testing-fraud-scheme

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

US v. AseraCare: Eleventh Circuit Affirms That Contradictory Clinical Judgments Alone Cannot Trigger FCA Liability

The Eleventh Circuit affirmed a three (3)-year-old district court ruling in *US v. AseraCare, Inc.*,[1] that a Medicare claim for hospice services cannot be deemed false under the False Claims Act ("FCA") based on a difference in clinical judgment. The decision instructs that a claim for hospice reimbursement cannot trigger FCA liability without an "objective falsehood" in the underlying clinical judgment. Moreover, any objective falsehood must be linked to an actual submitted claim to trigger FCA liability.

In 2008, three (3) relators filed a FCA complaint alleging AseraCare submitted "unsubstantiated hospice claims." The Department of Justice ("DOJ") subsequently intervened, and filed an amended complaint alleging that AseraCare had falsely certified certain patients as eligible for Medicare's hospice benefit based on "erroneous clinical judgments" and billed Medicare in violation of the false certification theory of FCA liability.

At trial, the DOJ identified a sample of about 120 AseraCare patients with allegedly false certifications. The DOJ then presented evidence to establish falsity through the opinion of a medical expert who disagreed with the original clinical determinations. The jury found that the majority of the sample claims were false.

Shortly thereafter, the district court ordered a new trial, finding that its jury instructions on falsity were incomplete. It then granted summary judgment for AseraCare. The district court recognized that the only evidence of falsity was a difference of opinion, but that difference, without more, was not enough to establish the falsity of a claim.

The Eleventh Circuit agreed with the district court's falsity analysis and affirmed its order for a new trial. The Eleventh Circuit then reversed the district court's summary judgment decision, reasoning that the DOJ should have had the opportunity to present evidence concerning an "objective falsehood." According to the court, examples of an objective falsehood include:

1. The certifying physician fails to examine the underlying medical records;
2. The certifying physician did not subjectively believe that the patient was terminally ill; or
3. The expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill, based on the relevant medical records.

Without evidence of an objective falsehood, an FCA claim is likely to fail as a matter of law.

In remanding the case to the lower court, the Eleventh Circuit acknowledged that the government might have evidence to suggest that AseraCare's certification procedures were flawed. Nevertheless, the court stated that the DOJ must link such evidence to the specific claims at issue in its case. In other words, proof that an actual false claim was filed cannot be solely based on a showing of general practices untethered to that claim.

The *AseraCare* decision is likely to have a widespread impact on hospice FCA litigation. The DOJ and relators in the Eleventh Circuit must now meet a higher falsity standard, one that preserves deference to the clinical judgment of a treating physician. The ruling will likely affect other FCA cases and investigations that center on differing medical opinions and clinical judgements.

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

Proposed Anti-Kickback and Stark Law Revisions Focused on Value-Based Care

Last month, the Centers for Medicare & Medicaid Services ("CMS") and the Department of Health and Human Service Office of Inspector General ("OIG") published highly anticipated proposed rules to modernize and clarify the Federal Stark Law, Anti-Kickback Statute ("AKS"), and Civil Monetary Penalties ("CMP") law (collectively, the "Proposed Rules").[2] The Proposed Rules aim to reduce regulatory barriers and transform the healthcare system from a volume- to value-based industry.

Stark Regulations

Under the current Stark Law, many arrangements designed to improve patient care coordination and improve quality are prohibited. The Proposed Rules would transform this standard, as it would create new, permanent exceptions to the Stark Law for value-based arrangements. Notably, these exceptions would apply broadly to care provided to all patients, not just Medicare beneficiaries.

Anti-Kickback Statute and Exception to the CMP Law

The AKS Proposed Rule would create three (3) new safe harbors for certain remuneration exchanged between or among eligible participants: (i) care coordination arrangements aimed at improving quality and outcomes; (ii) value-based arrangements with substantial downside financial risk; and (iii) value-based arrangements with full financial risk.

The AKS proposal also amends the definition of "remuneration" to incorporate a new exception for telehealth technologies furnished to in-home dialysis patients; includes a safe harbor for certain tools and supports furnished to patients to improve quality, outcomes, and efficiency; and proposes modifications to the existing safe harbor for local transportation.

Unless an extension is granted, public comments must be delivered to the agencies by 5 p.m. (EST) on December 31, 2019.

The HHS press release and proposed OIG and CMS rules can be found at :https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html

Submitted By: **Ashley Creech, Esq., & Elizabeth Scarola, Esq., *Epstein Becker & Green, P.C.***

LITIGATION UPDATES

Class Action Challenges Denials of Residential Treatment Based on Restrictive Clinical Guidelines

According to a complaint filed in Illinois federal court last week, Health Care Service Corporation ("HCSC") is applying overly restrictive clinical guidelines to deny medically necessary residential mental health and substance use disorder treatment to its insureds. Pamela Smith brought the action on behalf of her daughter and a putative class, all of whom were denied residential treatment based on the HCSC guidelines as developed by MCG Health.[3]

The suit alleges that HCSC, the country's fourth largest insurer, utilized the MCG Health clinical guidelines to de-emphasize residential treatment, or the length of stay at the level of care, and instead emphasized lower levels of care and shorter lengths of stay. Contrary to the accepted standards of medical practice, however, persistent and pervasive behavioral health disorders are not necessarily as effectively treated on a short-term or outpatient basis as they could be at the residential level of care. The restrictive coverage guidelines employed by HCSC, the suit alleges, violate the fiduciary duties owed to its members and beneficiaries under the Employee Retirement Income Security Act ("ERISA").

A similar action was recently filed in September by Smith's attorneys against Blue Cross Blue Shield of Florida ("BCBSF").[4] There, the complaint alleges that BCBSF's behavioral health plan administrator, New Directions Behavioral Health, adopted and inconsistently applied its own restrictive medical necessity criteria for treating eating disorders. Using criteria that was inconsistent with generally accepted medical practice, the suit alleges, New Directions repeatedly denied coverage for the plaintiff's residential treatment in violation of the fiduciary duties owed to BCBSF plan members and beneficiaries under ERISA.[5]

The case in Florida, and now in Illinois, come in the wake of the class victory in *Wit, et al. v. United Behavioral Health, et al.* earlier this year. There, patients denied coverage for treatment of their mental health and substance use disorders prevailed in a substantial fashion against United Behavioral Health ("UBH"). The court rebuked UBH for placing

its financial interests over the well-being of its members, finding UBH liable for breaching its fiduciary duty and for the plaintiffs' denial of benefits claim.[6]

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

PRIVACY UPDATES

HHS Releases Update to Security Risk Assessment Tool

Under the terms of the Health Insurance Portability and Accountability Act of 1996's ("HIPAA") Security Rule, covered entities and their business associates are required to conduct risk assessments to ensure compliance with HIPAA's administrative, physical and technical safeguards and thus determine whether patients' protected health information (PHI) could be at risk.[7] This assessment constitutes the cornerstone of any HIPAA compliance program and the basis for any remediation plan and without one, no program can be effective. A company can have great-looking policies written by the most expensive law firm in town, a privacy officer with a big team, and the most expensive and sophisticated IT systems; but, the truth is, if the company has not conducted a proper risk assessment, it really has not achieved much, a point emphasized by the United States Department of Health and Human Services' ("HHS") Office for Civil Rights ("OCR") several times in the past.[8]

To better help companies comply with HIPAA's Security Rule, HHS' Office of the National Coordinator for Health Information Technology ("ONC"), in collaboration with OCR, recently updated its *Security Risk Assessment Tool* ("SRA Tool"), which is now in its version 3.1. This new update includes several user-requested improvements, including but not limited to:

- An improved user interface,
- Threat and vulnerabilities rating,
- Incorporation of the National Institute of Standards and Technology (NIST) Cybersecurity Framework references,
- Custom assessment logic,
- Business associate and asset tracking,
- Ability to export detailed reports in Excel format for better visualization and extraction of data; and
- Minor fixes to address bugs and improve overall stability.

The updated SRA Tool, along with the new user guide, is an excellent resource for counsel and companies wishing to conduct thorough HIPAA risk assessments and is available for download at:
https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool.

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

OCR Imposes a $2.15 Million Civil Money Penalty Against Jackson Health System for HIPAA Violations

On October 23, 2019, the United States Department of Health and Human Services' ("HHS") Office for Civil Rights ("OCR") imposed a $2.15 million civil monetary penalty against Miami-based Jackson Health System ("JHS") for various violations of the Health Insurance Portability and Accountability Act of 1996's ("HIPAA") Security and Breach Notification Rules between 2013 and 2016. OCR's investigation revealed that JHS failed to provide timely and accurate notification of several breaches to HHS, and also failed to conduct enterprise-wide risk analyses, manage identified risks to a reasonable and appropriate level, regularly review information system activity records, and properly segment access to patient ePHI to the minimum necessary to allow its workforce to accomplish their job duties. The charges were not contested by JHS and the penalty has been paid in full as of this date. This is yet another showing that HIPAA enforcement is alive and kicking and is likely to continue for the foreseeable future.

The full OCR press release is available at:
https://www.hhs.gov/about/news/2019/10/23/ocr-imposes-a-2.15-million-civil-money-penalty-against-jhs-for-hipaa-violations.html

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

REGULATORY UPDATES

FDA Issues New Draft Guidance for Staff and Industry on Drug Products Labeled as Homeopathic.

On October 24, 2019, the Food and Drug Administration ("FDA") issued a new draft guidance for staff and industry on drug products labeled as homeopathic, describing how it intends to prioritize enforcement and regulatory actions for such products in the United States. In this regard, the draft guidance has noted that: (i) homeopathic drugs fall within the definition of "drug" contained in section 201(g)(1) of the Food Drug & Cosmetic Act[9] and, as such, fall within the jurisdiction of the FDA; and (ii) data shows that there has been an increase in situations in which homeopathic drugs have posed significant risks to patients even though the product labeling and ingredient formulation appeared to meet the conditions of Compliance Policy Guide CPG 400.400, issued in May 1988 by the Center for Drug Evaluation and Research ("CDER").

As in other instances, FDA intends to use a risk-based approach to the enforcement and regulation of the manufacturing, distribution and marketing of homeopathic drugs. In this regard, FDA has identified certain categories of homeopathic drugs that it believes may pose potential higher risks to public health and will therefore prioritize enforcement and regulatory actions with respect to them, namely:

1) Products with documented reports of injury that, after evaluation, raise potential safety concerns;
2) Products that contain or purport to contain ingredients associated with potentially significant safety concerns,
3) Products for routes of administration other than oral and topical,
4) Products intended to be used for the prevention or treatment of serious and/or life-threatening diseases or conditions,
5) Products for vulnerable populations such as immunocompromised individuals, infants and children, the elderly or pregnant women, and
6) Products with significant quality issues such as contamination with foreign materials or micro-organisms.

The full FDA draft guidance, which is open to comments from the public until December 24, 2019, is available at:
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-labeled-homeopathic-guidance-fda-staff-and-industry

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

Florida Law Restricts Enforceability of Certain Physician Restrictive Covenants

To retain top talent and to protect company trade secrets and other proprietary information, there has been a substantial increase in the number of employers requiring employees to sign non-compete agreements. The healthcare industry has not been immune to this trend. In fact, it has become a common practice for healthcare organizations hiring physicians to include restrictive covenants in employment agreements prohibiting such physicians from moving to a competing medical practice or opening a practice of their own. In Florida, restrictive covenants have typically been held valid and enforceable where an employer "has established that the restraint is reasonably necessary to protect the legitimate business interest"[10] and the restrictive covenant was ". . . within a reasonably limited time and area."[11] However, the Florida legislature recently enacted a law restricting the enforceability of non-compete agreements with certain types of physicians, effectively changing the landscape of restrictive covenants.

Specifically, House Bill 843 made several changes to existing law, including the addition of Section 542.336, Florida Statutes, titled "Invalid restrictive covenants." This new addition to Chapter 542, Florida Statutes, provides that:

> *A restrictive covenant entered into with a physician who is licensed under chapter 458 or chapter 459 and who practices a medical specialty in a county wherein one entity employs or contracts with, either directly or through related or affiliated entities, all physicians who practice such specialty in that county is not supported by a legitimate business interest. The Legislature finds that such covenants restrict patient access to physicians, increase costs, and are void and unenforceable under current law. Such restrictive covenants shall remain void and unenforceable for 3 years after the date on which a second entity that employs or contracts with, either directly or through related or affiliated entities, one or more physicians who practice such specialty begins offering such specialty services in that county.*[12]

In other words, Florida law now provides that a non-compete agreement between a physician (a Medical Doctor or Doctor of Osteopathic Medicine) who practices a medical specialty and an entity that employs all physicians who practice that medical specialty in the same county is void and enforceable on its face. The law goes on to state that such non-compete agreement will remain void and unenforceable against such physicians for three (3) years after a second employer enters the market in that county.

While the new law applies only to physicians practicing medicine in rural areas, it is unknown whether the Florida legislature will eventually broaden this prohibition to impact restrictive covenants for physicians practicing in non-rural areas and/or restrictive covenants for other types of healthcare providers. For that reason, practitioners are encouraged to proactively monitor this topic during future legislative sessions. With regards to the current landscape, practitioners with clients in rural areas should evaluate their client's non-competition agreements to ensure that applicable restrictive covenants do not run afoul of Section 542.336, Florida Statutes. Chapter 542, Florida Statutes, generally provides that non-competition agreements must be:

- reasonable in time, area, and line of business (courts presume a restraint of 6 months or less to be reasonable in time and anything more than 2 years in duration to be unreasonable with respect to restrictive covenants enforced against former employees, not associated with a sale);
- not contrary to public policy; and
- reasonably necessary to protect a legitimate business interest.[13]

Submitted By: **Tadena Simpson, Esq., *Envison Rx***

[1] *U.S. v. AseraCare, Inc*., No. 16-13004 (11th Cir. Sept. 9, 2019).
[2] Medicare Program; Request for Information Regarding the Physician Self-Referral Law, CMS, 83 FED. REG. 29,524 (June 25, 2018); Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, OIG, 83 FED. REG. 43,607 (Aug. 27, 2018).
[3] *Smith v. Health Care Svc. Corp. & MCG Health, LLC*, No. 1:19-cv-07162 (N.D. Ill. Oct. 31, 2019).
[4] To read additional information about this case, see Sam Winikoff, Esq., "Class Action Seeks to Challenge Systematic Denial of Behavioral Health Benefits," Florida Bar Health Law Section Monthly Updates (July – August 2019 Health Law Updates), *available at* https://www.flabarhls.org/news/health-law-monthly-updates.
[5] *Hering v. New Directions Behavioral Health LLC et al*., No. 6:19-cv-01727 (M.D. Fla. Sep. 5, 2019).
[6] *Wit, et al. v. United Behavioral Health, et al*., No. 3:14-cv-02346 (N.D. Ca. Feb. 28, 2019).
[7] *See* 45 C.F.R. § 164.308(a)(1)(ii)(A).
[8] Most recently, Jackson Health System of Miami, Florida, got slapped with a $2.15 MM civil penalty from OCR for, among other violations, not conducting an enterprise-wide risk assessment. *See* https://www.hhs.gov/about/news/2019/10/23/ocr-imposes-a-2.15-million-civil-money-penalty-against-jhs-for-hipaa-violations.html.
[9] *See* 21 U.S.C. § 321(g)(1). Note that the definition of "drug" expressly includes products recognized in the Homeopathic Pharmacopeia of the United States ("HPUS") or any of their supplements.
[10] *See USI Ins. Servs. Of Fla. Inc. v. Pettineo*, 987 So. 2d 763, 766 (Fla. 4th DCA 2008); *see also* FLA. STAT. § 542.335(1)(b) ("The person seeking enforcement of a restrictive covenant shall plead and prove the existence of one or more legitimate business interests justifying the restrictive covenant.").
[11] *See* FLA. STAT. § 542.33; *see also id.* § 542.335(1).
[12] *See id.* § 542.336.
[13] *See id*. § 542.335(1)(b) (legitimate business interest includes, but is not limited to: trade secrets, as defined in s. 688.002(4); valuable confidential business or professional information that otherwise does not qualify as trade secrets; substantial relationships with specific prospective or existing customers, patients, or clients; customer, patient, or client goodwill associated with **a.** an ongoing business or professional practice, by way of trade name, trademark, service mark, or "trade dress;" **b.** a specific geographic location; or **c.** a specific marketing or trade area; and extraordinary or specialized training).