September 2019

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with July through August 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:

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

Erin J. Hoyle, Esq., ***Carlton Fields***

Jason Mehta, Esq. & Travis Lloyd, Esq., ***Bradley Arant Boult Cummings LLP***

Martin R. Dix, Esq. & Steven A. Grigas, Esq., ***Akerman LLP***

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

Thank you,

Jamie Gelfman, Esq., ***Nelson Mullins Broad and Cassel*****, HLS Editor in Chief**

Ashley Brevda, Esq., Corp Counsel/Chief Compliance Officer, ***Oncology Analytics, Inc.*****, HLS Team Editor**

Trish Huie, Esq., ***Patricia A. Huie, PLLC*****, HLS Team Editor**

ADMINISTRATIVE LAW UPDATES

DOH's Initiates Rulemaking to Provide Out-of-State Telehealth Practitioners the Ability to Treat Florida Patients

On June 25, 2019, Governor DeSantis signed House Bill 23 (2019) into law ("HB 23"). The bill, as implemented, sets additional guidelines and requirements for the use of telehealth services in the state of Florida. As part of those requirements, HB 23 created Section 456.47(4), Florida Statutes, which sets out the general registration requirements for out-of-state telehealth providers. Specifically, Section 456.47(4)(b) states that:

> The board, or the department if there is no board, shall register a health care professional not licensed in this state as a telehealth provider if the health care professional:
>
> 1. Completes an application in the format described by the department;
> 2. Is licensed with an active, unencumbered license that is issued by another state, the District of Columbia, or a possession or territory of the United States and that is substantially similar to a license issued to a Florida-licensed provider specified in paragraph (1)(b);
> 3. Has not been the subject of disciplinary action relating to his or her license during the 5-year period immediately prior to the submission of the application;
> 4. Designates a duly appointed registered agent for service of process in this state on a form prescribed by the department; and
> 5. Demonstrates to the board, or the department if there is no board, that he or she [maintains professional liability coverage or financial responsibility as required by Florida law.]

On September 5, 2019, the Department of Health ("DOH") published a Notice of Development of Rulemaking ("Notice") for Rule 64B-9.008, Florida Administrative Code. As stated in the Notice, the purpose and effect of the rulemaking is, in part, to "provide a form for out-of-state telehealth providers to register with the appropriate board, or the department, if there is no board, prior to providing telehealth services to patients located in this state, as required by recently enacted legislation." Development of the form still needs to follow the rule development process in Chapter 120, Florida Statutes. Once the form is finalized and adopted by the DOH, the form will allow out-of-state healthcare providers to begin the registration process to provide telehealth services to Florida residents.

Submitted By: **Angelina Gonzalez, Esq., *Panzer, Maurer & Maynard, P.A.***

FRAUD & ABUSE UPDATES

Florida Hospitals Tied to $57 Million Money Laundering Scheme

Two Florida hospitals are among those linked to a $57 million money laundering conspiracy associated with a pass-through billing scheme.

According to the Department of Justice ("DOJ"), Kyle Marcotte, owner of a Jacksonville substance abuse treatment center, pleaded guilty in July 2019 for his role in the conspiracy. Marcotte's guilty plea included several admissions highlighting allegedly improper billing practices at multiple rural hospitals.

In 2015, Marcotte entered into an agreement with the owner of an unidentified clinical laboratory. Under the agreement, Marcotte's treatment center sent patient urine samples to the laboratory for drug testing in exchange for 40% of the insurance reimbursement. To receive higher reimbursement for the testing, the lab owner arranged with the managers of two rural Florida hospitals to have the claims billed to private insurers through the hospitals' in-network payer contracts.

Marcotte also admitted to arranging drug testing billed through the hospitals for other treatment centers in exchange for 10% of the insurance payments. The other facilities received 30% of the reimbursements.

When the lab owner subsequently acquired several rural hospitals in Georgia, the pass-through billing scheme continued at those locations. Marcotte continued to broker deals with other treatment centers for testing billed through the Georgia hospitals.

The DOJ asserted that Marcotte paid over $50 million from his company's bank accounts to at least 88 companies and individuals who supplied urine samples for testing. As part of Marcotte's plea agreement, he agreed to forfeit $10.2 million. Marcotte's sentencing has not yet been scheduled.

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

LEGISLATIVE UPDATES

Significant Changes to Florida's Patient Brokering Act: Uncertainty Lies Ahead

Recent legislative and judicial developments have the potential to significantly impact healthcare providers doing business in Florida. Until some of the uncertainty is resolved, healthcare providers should avoid arrangements that might trigger scrutiny under the state's Patient Brokering Act. Providers may also consider seeking declaratory judgments and advisory opinions from state regulators.

Historical Background

Florida, like many other states, has a broad statutory prohibition against patient brokering and splitting of fees in the healthcare context. The state's Patient Brokering Act, Section 817.505, Florida Statutes, criminalizes any "offer or pay[ment of] any commission, bonus, rebate, kickback, or bribe . . . to induce the referral of patients or patronage to or from a health care provider or health care facility." The statute appears to track the federal Anti-Kickback Statute ("AKS") and seems to limit nothing more than what is already proscribed at the federal level.

Even the exemptions in the state statute seemingly track the AKS. For example, until earlier this summer, the state statute explicitly exempted "[a]ny discount, payment, waiver of payment, or payment practice not prohibited by 42 U.S.C. § 1320a-7b(b) [the AKS] or regulations promulgated thereunder." Conduct that fell under federal "safe harbors" was not criminalized under the state statute.

For all practical purposes, healthcare providers in Florida could simply follow federal AKS guidance to avoid additional Florida regulatory scrutiny. This may no longer be applicable for at least two reasons.

Recent Legislative Changes

First, earlier this summer, the Florida legislature modified the statute in response to a broader crackdown on improper arrangements related to the opioid crisis in order to limit the scope of exceptions. Now, the above exemption has been narrowed to exempt only practices "expressly authorized by 42 U.S.C. § 1320a-7b(b) or regulations adopted thereunder." The statute now only exempts those practices "expressly authorized" as opposed to those "not prohibited."

While this change might seem immaterial, the potential legal ramifications are significant. In particular, the AKS does not "expressly authorize" practices or arrangements. Rather, the AKS simply provides "safe harbors" defining conduct that is not prohibited.

It is unclear whether the state legislature was aware of the potential impact of the change at the time of the amendment's passage. While the law was amended to bolster enforcement efforts by state prosecutors, the unintended consequences may have a chilling effect on healthcare providers doing business in Florida.

Recent Judicial Decision

The second change might prove even more meaningful. Shortly after the legislative amendment, an appellate court in Florida interpreted the same patient brokering statute in *State of Florida v. James Francis Kigar*, which may result in even more chilling effects. The appellate court effectively removes the ability of healthcare providers to rely on the "advice of counsel" defense as a bar to enforcement proceedings.

In *Kigar*, a defendant was charged with over 100 counts of patient brokering. On the eve of trial, the government moved to exclude any evidence of an "advice of counsel" defense. The government argued that the patient brokering statute was one of general intent, not specific intent, and as such, the government suggested that there was no room for an "advice of counsel" defense.

The appellate court, in a matter of first impression, agreed with the government. The court found that in prosecuting a patient brokering act case the government was not required to prove the defendant had a specific improper intent to violate the statute. In other words, the court held that prosecutors did not need to prove a "heightened or particularized intent beyond the mere intent to commit the act itself." Given this finding – that the patient brokering act is a general intent statute – the court followed long-standing judicial principles to find the "advice of counsel" defense to be inapplicable. As such, the appellate court granted the government's motion to exclude any advice of counsel defense.

Until *Kigar*, a bedrock principle was that faithfully soliciting – and following – legal advice was a bar to any kickback prosecution in Florida, and that *Kigar* significantly casts that principle into doubt.

Effect of Statutory Amendments and *Kigar*

At the moment it is unclear whether the Florida legislature will revisit the statutory changes or whether other courts will follow the *Kigar* opinion. However, until the issues are revisited, healthcare providers doing business in Florida would be well-served to tread lightly when structuring arrangements to comply with the Patient Brokering Act.

Submitted By: **Jason P. Mehta, Esq., and Travis G. Lloyd, *Bradley Arant Boult Cummings LLP***

LITIGATION UPDATES

Class Action Seeks to Challenge Systematic Denial of Behavioral Health Benefits

A proposed class action filed this week seeks to challenge Blue Cross Blue Shield of Florida ("BCBSF") and New Directions Behavioral Health's guidelines for covering residential treatment services.[1]

Susan Hering brought the suit on behalf of her daughter, who suffers from generalized anxiety disorder and anorexia nervosa. The suit claims that New Directions, BCBSF's behavioral health claims administrator, violated the Employee Retirement Income Security Act ("ERISA") through its use of improper and overly restrictive coverage guidelines. The complaint alleges that New Directions adopted and inconsistently applied medical necessity criteria to the generally accepted standards of behavioral health care for eating disorders. Using its inconsistent criteria, New Directions repeatedly denied coverage for Hering's residential treatment, despite the treatment ostensibly being covered under her BCBSF plan and conforming to generally accepted standards of care.

By using its allegedly inconsistent guidelines to systematically deny claims, *Hering* argues that BCBS and New Directions breached their fiduciary duties to plan members and beneficiaries in violation of ERISA.

Hering is part of a larger national effort for patients and health providers to guarantee insurers' compliance with federal and state behavioral health parity laws. Earlier this year, Hering's attorneys, on behalf of a class of patients who were denied coverage for their mental health and substance use disorders, prevailed against United Behavioral Health ("UBH").[2] The court rebuked UBH for placing its financial interests over the well-being of its insureds, finding UBH liable for breach of its fiduciary duty and for the plaintiffs' denial of benefits claim.

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

REGULATORY UPDATES[3]

Florida Procurement Law: Competitive Solicitations and Bid Process[4]

Overview

Sections 287.017 (purchasing thresholds) and 287.057 (procurement methods), Florida Statutes, establish Florida's competitive procurement of commodities or contractual services. These procedures apply to all state agency ("Agency") procurements. Local governments may adopt their own procedures. Three common procurement methods are: Invitation to Bid ("ITB"), Request for Proposal ("RFP") and Invitation to Negotiate. ("ITN"). An ITB is where the Agency tells the bidder the goods or services it wants and asks for a price bid. An RFP is where the Agency asks for both a proposal and price bid. The ITN calls for a written response to established criteria under which formal negotiations may be held. An Agency may have other less common procurement processes pursuant to Chapter 287, Florida Statutes.

Protests

Florida's Administrative Procedures Act, Section 120.57(3), Florida Statutes, and Chapter 28-110, Florida Administrative Code, govern competitive bid disputes of State procurements. Avenues of protest that may be used in a bid dispute include a challenge to the specifications ("Spec Challenge") or a challenge to a decision or intended decision (the award) made by an Agency. Notice for either of these challenges must be made to the Agency within 72 hours of the Agency's posting of the information.

1. **Issues for Protests**

- Any party that wishes to challenge the terms, conditions, criteria, or specifications of the procurement as unfair, biased, not necessary, impossible to meet, or other substantive objection, must file a notice of intent to challenge within 72 hours of posting of the information or the issue is forever waived. A protest bond and formal protest must also be filed within 10 days of the filing of the notice of protest.
- Any party adversely affected by an award decision or intended decision shall file with the Agency a notice of intent to protest in writing within 72 hours after the posting of the bid tabulation or after receipt of the notice of the Agency decision or intended decision. Section 120.57(3), Florida Statutes.

2. Filing of the Protest

- Within ten (10) calendar days after the notice of intent to protest is filed, a party shall file a formal written notice of protest with the contact person listed in the bid solicitation; and
- Post a bond payable to the Agency. In lieu of a bond, a cashier's check or money order may be submitted to the contact person.
- Upon receipt of a timely filed formal written notice of protest and accompanying bond the review and/or award process usually is stopped until the protest is resolved. Exceptions may be made where stoppage may affect health safety, welfare of residents in the state.

3. Posting of Protest Bond per Sections 287.042(2) (c) and 120.57(3)(b), Florida Statutes

- Parties intending to protest shall post with the Agency at the time of filing the formal written protest, a bond payable to the Agency in an amount equal to one (1) percent of the Agency's estimate of the total volume of the contract. The bond should be submitted using a Procurement Protest Bond Form, PUR 7062, obtained from the Department of Management Services, Division of Purchasing.
- Upon completion of the administrative hearing process and any appellate court proceedings, the prevailing party shall recover all costs and charges excluding attorney's fees.

4. Required Content of a Formal Written Notice of Protest

- The name and address of the appropriate office with which the protest will be filed;
- The name and address of the party filing the protest and an explanation of how its substantial interests have been affected;
- A statement of how and when the party filing the protest received notice of the bid solicitation or notice of the Agency's intended or actual contract award;
- With particularity, the facts and law upon which the protest is based;
- A statement of all issues of disputed material facts;
- A concise statement of the ultimate facts alleged, as well as the rules and statutes which entitle the party filing the protest to relief;
- A demand for relief to which the party deems itself entitled; and
- Any other information which the party contends is material.

5. Resolution of the Protest

- Upon receipt of the formal written notice of protest and accompanying bond, the contract manager must attempt to resolve the protest informally. The contract manager has seven (7) working days after receipt of the formal written notice of protest to resolve it through mutual agreement.
- Any decision by the Agency to change an intended award, or to reject all bids or proposals as a result of discussions during the settlement period must include a new notice of rights that affords affected parties an opportunity to file a challenge to the new action.
- If the protest is not resolved by mutual agreement within seven (7) working days of receipt of the formal written protest, and if there is no disputed issue of material fact, an informal proceeding pursuant to Section 120.57(2), F.S. shall be held.
- If the protest is not resolved by mutual agreement within seven (7) working days of receipt of the formal written protest, and if there is a disputed issue of material fact, the formal

written protest shall be referred to the Division of Administrative Hearings ("DOAH") for further proceedings pursuant to Sections 120.569 and 120.57(1), Florida Statutes.

6. Hearing

- A formal proceeding, or formal hearing pursuant to Section 120.57(1), Florida Statutes, at DOAH before an Administrative Law Judge ("ALJ"), is held within 30 days of receipt of the formal written protest unless all parties agree to a waiver of the statutory timeframe.
- The DOAH proceeding is *de novo*.
- A protestor has the burden of proof and must prove the Agency's action was contrary to the Agency's governing statutes, rules or policies, or the procurement specifications. Section 120.57(3)(f), Florida Statutes.
- A protestor also must show that the Agency's decision was clearly erroneous, contrary to competition, arbitrary, or capricious.

7. Order (Formal 120.57 Hearing)

- Within ten (10) days after the transcript is prepared, each party may file a proposed recommended order with the ALJ, outlining proposed findings of fact and conclusions of law.
- After reviewing the record and the proposed recommended orders, the ALJ enters a recommended order within 30 days.
- Parties can file exceptions with agency within 10 days of the recommended order being issued.
- Agency should enter a final order within 30 days after receipt of the ALJ s recommended order.
- Agency's final order is subject to judicial review via appeal to the District Court of Appeal.
- There is no stay during an appeal of the final order.

Summary

The procurement process is designed to ensure fair competition and to secure the best possible value at the lowest cost to the Agency. Because of the expedited nature of the procurement process, and its inherent complexities, applicants need be both well informed and well represented. Consideration should be given to retaining knowledgeable counsel early in the process so as to assist in the review and analysis of the proposal and defense of the applicant's position. The above is a general summary of Florida law and it should not be relied upon as legal advice or recommendation.

Submitted By: Steven A. Grigas, Esq. & Martin R. Dix, Esq., *Akerman LLP*

---

[1] *Hering v. New Directions Behavioral Health LLC et al*, No. 6:19-cv-01727 (M.D. Fla. Sep. 5, 2019).

[2] *Wit et al v. United Behavioral Health*, No. 3:14-cv-02346 (N.D. Ca. Feb. 28, 2019).

[3] *Editor's Note:* The following Update is not a typical publication for the HLS Updates in that it is not a summary of a recent development in health care law. However, the Editors believe that this topic may be informative and useful for many of its readers.

[4] *This Update is a reprint of a September 2019 Client Advisory issued by Akerman LLP.*