THE FLORIDA BAR

Health Law Section Newsletter

THE RESOURCE FOR FLORIDA HEALTH LAW

The Florida Bar Health Law Section

Vol. XVII, No. 16 www.flabarhls.org Winter 2018

INSIDE:

– Getting to Know –

Cynthia Anne Mikos

Health Law Section Member Spotlight

Cynthia Anne Mikos is a Co-Chair of the Health Care Team at her firm, Johnson Pope Bokor Ruppel & Burns, LLP. Ms. Mikos is Board Certified in Health Law by the Florida Bar Board of Legal Specialization and Education. She is a past Chair of our section, and was a member of the executive committee for 10 years. She has represented licensed health care professionals and facilities throughout Florida for over 20 years.

Please tell us how you got started in health law.

Prior to law school, I spent more than a decade working in health care, first as a nurse and then as a manager of home health agencies. So, health law was a natural fit because I understood the industry from multiple perspectives. Barbara Pankau, one of Florida's first health care lawyers, served as Florida counsel to the home care company where I worked and I was lucky enough to clerk with her while completing law school. She hired me upon graduation and I have practiced health law ever since.

What made you decide to go to law school after already having a career as a nurse?

I was struck by how the health care industry as a whole, and home health care in particular, was driven by federal regulation. In the delivery of home care, we often strained to find a way to get a patient what they needed within the parameters of what was reimbursable. I found the regulatory framework fascinating, initially wanting to understand it from a public policy angle and later, as a practicing attorney, from the application of the law to real life context. I continue to find the intersection between the needs of the health care delivery system and the limitations of the law intriguing and enjoy helping my clients navigate the maze.

You were also an executive of a Fortune 100 home health company. Please tell us how that experience benefits your law practice today.

I learned how to work in a corporate environment and the importance of the operations team to the success of the business venture. The operations people need clear guidance to steer the company properly. Based on my prior management experience, I try to avoid long recitations of the law that do not give practical advice and recommendations. I also attempt to gather sufficient facts about the nature of the problem that caused the client to seek legal advice so I can address the real life problems the client is facing.

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CYNTHIA ANNE MIKOS

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You have practiced in both larger and smaller firms. What do you like best about each setting?

Small firms offer independence. Large firms have deep resources. Today, I am pleased to practice in a mid-sized firm that combines the advantages of both.

What made you decide to become board certified in health law, and do you think it has been a benefit to your practice?

Board certification to health care practitioners is an integral part of their professional lives that demonstrates their competency in the field. I sought board certification in health law as soon as I was eligible and have maintained the certification continuously. In my experience, it gives clients a level of comfort that you understand their industry and has been an asset to my practice.

What do you like best about being a health lawyer?

I am seldom, if ever, bored. I like the variety of the issues that arise, the creative problem-solving aspects of the practice, and assisting those who are caring for others in the health care industry.

If you could have any job (besides being an attorney) and money were no object, what would you do?

Own a bookstore, be a writer, a book reviewer, an English literature teacher, a competitive Scrabble player or something similar. Lawyering lets me play with words, read, and get paid. If money were no object, I could forget about the economics of it all.

What advice would you have for young lawyers who want to go into health law?

Work in the health care industry first so you understand what the clients face.

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This article is part of a series of interviews highlighting members of our section. Please contact the editor, Shannon B. Hartsfield at shannon.hartsfield@hklaw.com to recommend someone who should be featured in an upcoming edition. Ms. Hartsfield practices at Holland & Knight LLP. She is Board Certified in Health Law by the Florida Bar Board of Legal Specialization and Education.

New Florida Direct Primary Care Law Encourages Innovative Practice Model

By: Ann Breitinger

Florida's new Direct Primary Care (DPC) model law took effect July 1, 2018. With DPC models on the rise, Section 642.27 *Florida Statutes* finally allays physicians' (and their lawyers') concerns that such models could be considered insurance and, therefore, subject to the Florida Insurance Code. The new statute also sets forth specific requirements for DPC contracts between physicians and patients.

Generally, DPC practice models eliminate the fee-for-service payment structure, thereby cutting out third-party payors. Instead DPC practices accept one monthly flat fee intended to cover all of the comprehensive primary care needs of the patient for the month.

Advocates of the DPC practice model tout the model as a means to allow physicians to focus on patient care rather than the financial incentives of increased procedures and tests. Other advantages to the DPC model include increased time spent with the patient and unhurried interactions. Some DPC models also allow patients 24/7 access to their physicians via cell phone and same day appointments as additional benefits.

Section 642.27 *Florida Statutes* specifies that DPC agreements do not constitute insurance and are not subject to the Florida Insurance Code and provides requirements for agreements between the physician and patient. The law pertains to medical doctors, doctors of osteopathy, chiropractors and nurses.

Pursuant to the new law, a DPC agreement must:

- Be in writing.
- Be signed by the primary care provider or an agent of the primary care provider and the patient, the patient's legal representative, or the patient's employer.
- Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.
- Describe the scope of primary care services that are covered by the monthly fee.
- Specify the monthly fee and any fees for primary care services not covered by the monthly fee.
- Specify the duration of the agreement and any automatic renewal provisions.
- Offer a refund to the patient, the patient's legal representative, or the patient's employer of monthly fees paid in advance if the primary care provider ceases to offer primary care services for any reason.
- Contain, in contrasting color and in at least 12-point type, the following statement on the signature page: "This agreement is not health insurance and the primary care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any primary care services covered by the agreement. This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the Patient Protection and Affordable Care Act, 26 U.S.C. s. 5000A. This agreement is not workers' compensation insurance and does not replace an employer's obligations under chapter 440."

Ann Breitinger practices health care and corporate law at Blalock Walters, P.A. in Bradenton. She can be reached at 941-748-0100 or abreitinger@blalockwalters.com

Did You Know? CON Law in Florida - Look to CON Exemptions for Path of Least Resistance

By: Corinne Porcher

Winston Churchill famously declared "victory will never be found by taking the path of least resistance." It is assumed Churchill was commenting on something other than Florida's Certificate of Need Law. As any health care attorney knows, obtaining a CON from AHCA can be an expensive and time-consuming venture for clients. But what health care providers *should* know is just how many projects are exempted from CON review altogether. Attorneys familiar with these exemptions can navigate their clients through the relatively simple CON exemption process to adjust or modify their health care licenses as needed without litigation from competitors.

Section 408.036(1), *Florida Statutes*, provides a list of health care facilities and projects that remain subject to CON review. However, the list has dwindled over the years, as projects formerly requiring CON review have been simply deleted from the list. Prominent examples include Medicare-certified home health agencies, open heart surgery programs, burn units, cardiac catheterization programs and capital expenditures for major medical equipment.

In addition to the removal of projects from the CON review listing, Section 408.036(3), *Florida Statutes*, expressly exempts certain projects from CON review, including: the addition of hospice or swing beds in rural hospitals; conversion of certain acute care beds to skilled nursing beds in rural hospitals; addition of nursing home beds in specific circumstances; the addition of comprehensive rehab beds; establishment of neonatal intensive care units; the addition of mental health services or beds if the licensee commits to serving Medicaid and/or charity care patients at a level equal to, or greater than, the district average; and replacement nursing homes within five miles of the original site within the same subdistrict.

A licensee need only provide written "notification" to AHCA, pursuant to section 408.036(5), Florida Statutes, in order to establish a replacement facility within a one-mile radius of the original location, terminate a health care service, and add or delicense beds. The conversion of one type of mental health bed to another type does not require a CON exemption request per rule 59C-1.005(i)(8), *Florida Administrative Code*.

It is important to note that AHCA must approve all exemptions and "notifications" before changes can be implemented by the licensee. At a minimum, exemptions require the facility to submit a written request, along with a $250 fee, to the CON Unit pursuant to rule 59C-1.005, Florida Administrative Code. The request must cite to the statutory exemption requested and provide the name of the facility and licensee making the request, project costs and gross square footage, proposed licensed bed capacity and other information that may be required depending on the exemption type.

Once the CON approves an exemption request or notification, the licensee must obtain approval from the Office of Plans and Construction for the proposed project. The last step in the exemption/notification process is submitting a Health Care Licensing Application to the Hospital and Outpatient Services Unit to have the changes reflected on the facility's license.

Corinne Porcher practices Administrative and Health Care Law at Smith & Associates in Tallahassee. She primarily represents health care facilities in a variety of regulatory and licensing matters throughout Florida.

Our "Did You Know?" series focuses on issues that are of importance to all Florida health lawyers.

Sexual Assault of a Patient: Medical Malpractice or Ordinary Negligence?

By: Ashley V. Makris

Merely because a wrongful act occurs in a medical setting does not necessarily mean that it involves medical malpractice, and whether a claim sounds in medical negligence or ordinary negligence can have significant ramifications. For example, medical negligence claims have a shorter statute of limitations period than ordinary negligence claims – two years versus four years, respectively. See § 95.11(3)(a), 4(b), Fla. Stat. Moreover, employers sometimes have success evading claims related to sexual assaults by employees in ordinary premises liability claims, while such is not always the case in medical negligence claims. See Iglesia Cristiana La Casa Del Senor, Inc. v. L.M., 783 So. 2d 353, 357 (Fla. 3d DCA 2011); see also Nazareth v. Herndon Ambulance Service, Inc., 467 So. 2d 1076, 1078 (Fla. 5th DCA 1985) ("Generally, sexual assaults and batteries by employees are held to be outside the scope of an employee's employment, and therefore, insufficient to impose vicarious liability on the employer.").

The type of negligence involved in a case also impacts insurance coverage potentially available. For example, in *Alicea Enterprises, Inc. v. Nationwide Ins. Co. of Am., Inc.,* a woman brought suit against a pharmacy for supplying an abortifacient drug which allegedly caused her to have a miscarriage. 252 So. 3d 799 (Fla. 2d DCA 2018). Nationwide issued a general liability insurance policy to Alicea Enterprises, which owned and operated the defendant pharmacy. Nationwide contended the allegations against the pharmacy arose out of the "professional '[s]ervice, treatment, advice or instruction in the practice of pharmacy.'" Id. at 801. As a result, Nationwide contended it had no duty to defend nor indemnify the pharmacy because the policy expressly excluded coverage for professional services. Id.; see also Lindheimer v. St. Paul Fire and Marine Insurance Co., 643 So. 2d 636, 638-39 (Fla. 3d DCA 1994) (considering whether a dentist's sexual assault on a patient came within the professional services coverage of his professional liability insurance policy and holding that the dentist's sexual assault was not causally connected to the provision of professional services, regardless of the pretense of medical care used by the insured to catch his victim unaware).

Prospective medical malpractice plaintiffs must also comply with the presuit requirements set forth in Chapter 766, *Florida Statutes.* These stringent standards persist even after a lawsuit is filed. For example, medical experts testifying to the standard of care must meet specific, statutory qualifications under section 766.102, *Florida Statutes*. The presuit screening requirements apply to claims "arising out of the rendering of, or the failure to render, medical care or services." § 766.106(1)(a), Fla. Stat. Stated differently, the presuit screening requirements apply "if the wrongful act is directly related to the improper application of medical services and the use of professional judgment or skill." Corbo v. Garcia, 949 So. 2d 366, 368 (Fla. 2d DCA 2007) (quoting Lynn v. Mount Sinai Med. Ctr., 692 So. 2d 1002, 1003 (Fla. 3d DCA 1997)). Whether the action arises out of healthcare services, including medical, dental or surgical care, is a key inquiry. Id.

While common sense would seem to indicate a sexual assault cannot be related to the "application of medical services" and the "use of professional judgment or skill," at least one court has found it can. The plaintiff in *St. Joseph's Hosp., Inc. v. Doe* alleged she was sexually assaulted by a hospital employee while she was a patient in the hospital's mental health care facility. 208 So. 3d 1200 (Fla. 2d DCA 2017). The hospital moved for summary judgment due to the plaintiff's failure to presuit her claims, which the hospital believed sounded in medical negligence. Id. at 1201. The Second District Court of Appeal upheld the trial court's denial of the hospital's motion for summary judgment as to the first count of the complaint, which alleged negligent supervision and negligent security. Id. In doing so, the Court explained there was "nothing in these allegations… involv[ing] medical care or services." Id. at 1202. However, the court reversed the trial court's denial as to the second count of the complaint which alleged the hospital failed to supervise and monitor its personnel, and to investigate her allegations. Id. at 1203-04. The court found these were specific requirements under Chapters 395 and 766, Florida Statutes, and thus were medical negligence claims. Id. In contrast, the Fourth District Court of Appeal reversed dismissal of a complaint for failure to comply with the presuit requirements after it determined a claim of sexual misconduct on the part of a physician during a medical examination did not arise out of negligent medical treatment. Burke v. Snyder, 899 So. 2d 336, 341 (Fla. 4th DCA 2005).

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SEXUAL ASSAULT

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Similarly, in *Buchanan v. Lieberman,* a trial court entered summary judgment for a defendant physician on the basis that the plaintiff's action was barred by the two-year statute of limitations for medical malpractice actions. 526 So. 2d 969, 970 (Fla. 5th DCA 1988). In reversing the trial court's decision, the Fifth District Court of Appeal found there were no allegations the defendant used his doctor-patient relationship to induce his patient to engage in sexual relations, and therefore this was a claim of ordinary negligence. Buchanan, 526 So. 2d at 973.

As this specific issue is still relatively uncharted territory, practitioners can seek guidance from similar appellate decisions which have focused on the requisite standard of care implicated by the plaintiff's allegations in determining whether a claim sounds in medical negligence, and thus requires compliance with Chapter 766, Florida Statutes. See, e.g., Acosta v. Healthspring of Fla., Inc., 118 So. 3d 246, 248-49 (Fla. 3d DCA 2013) (concluding that a hospital's failure to transport a patient timely did not implicate the medical negligence standard of care, and therefore sounded in ordinary negligence); *South Miami Hospital, Inc. v. Perez,* 38 So. 3d 809, 812 (Fla. 3d DCA 2010) (finding that a claim regarding a plaintiff who was left unrestrained and unattended in his hospital bed sounded in medical negligence because the allegations could only be proven through evidence that the provider's conduct fell below the prevailing medical standard of care); Joseph v. University Behavioral LLC, 71 So. 3d 913 (Fla. 5th DCA 2011) (finding that a claim by a patient who was attacked by another patient sounded in ordinary negligence because no psychiatric treatment decisions resulted in his exposure to the injury he suffered).

In April of 2018, the Florida Supreme Court amplified this approach by also focusing on the act from which the claim arises. In *Nat'l Deaf Acad., LLC v. Townes,* the Court concluded: "[W]e hold that for a claim to sound in medical malpractice, the act from which the claim arises must be directly related to medical care or services, which require the use of professional judgment or skill. This inquiry involves determining whether proving the claim requires the plaintiff to establish that the allegedly negligent act 'represented a breach of the prevailing professional standard of care,' as testified to by a qualified medical expert." 242 So. 3d 303, 311-312 (Fla. 2018). The court found that a patient who was injured during a tactical hold did not sound in medical negligence because it was employed, in part, by non-medical personnel. Moreover, since the hold was an attempt to stop the patient from injuring herself and others, it could not be said the hold was to ascertain her medical condition.

Although the definition of medical negligence appears simple, courts' interpretations vary among the jurisdictions. Because a court will evaluate each claim on a case-by-case basis, a practitioner should also carefully analyze the facts of each case before moving forward in the prosecution or defense of any negligence claim.

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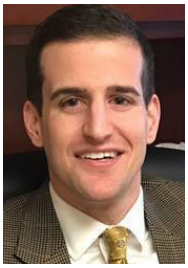
DMEPOS Marketing Dilemmas

By: Spencer E. Winepol



On televisions across America, nightly advertisements offer "free" medical items, including braces for the neck, knee, back, wrist, and more. Viewers are asked to call – or are called by – a 1-800 Number to qualify for these items. This is just one of the marketing efforts underpinning a more than $40 billion a year durable medical equipment industry. Other efforts include direct mailers, internet advertising, and cold calling for every medical product from diabetic strips to catheters.[1] DMEPOS companies located across the country use these methods to obtain clients, yet for those that are called by these toll free numbers, they may unknowingly be entering a lucrative game played with their Medicare numbers. Unwitting Medicare beneficiaries soon realize that "free" simply means their Medicare number is required. After answering a series of medical questions, being shuttled between phone calls, and telephonic doctors' appointments, this number has become marketable.

The buying and selling of marketable leads creates risk under the Federal Anti-Kickback Statute when a government funded health program is a payor, and under Florida's Patient Brokering Act, which extends these legal requirements to private healthcare payors.[2] Still, some DME suppliers sometimes entrust their marketing efforts to offshore marketing companies and call centers.

The DME supplier can be left to suffer the consequences of improperly acquired leads or noncompliant marketing activities. In addition to creating risk under federal and state anti-kickback laws, some of these actions also implicate the False Claims Act if the government can demonstrate that DME owners knowingly induced or pressured these patients into receiving durable medical equipment at no cost or a reduced cost. As a result, it is important that DME owners remain increasingly vigilant regarding the marketing companies with which they align themselves. Random quality control checks, recording calls (with caller permission), and ensuring that employees are trained in compliance are steps that can be taken to try to avoid violations.

Spencer E. Winepol is an attorney with De Varona Law located in Boca Raton, Florida and serves as outside transactional and litigation counsel to closely held businesses operating in highly regulated industries, namely healthcare and construction.

Endnotes

1 DME Suppliers must obtain a Medicare beneficiary's permission in order to call them, see 42 C.F.R. §424.57(c)(11) and 42 U.S.C. §1395m(a)(17), though many marketing companies disregard this requirement.

2 Unless the purchase and sale arrangement takes place within a Safe Harbor to the Federal Anti-Kickback Statute or falls within other recognized exceptions, regulators are likely to look unfavorably upon the purchase and sale of DME leads. See Jeffrey S. Baird, "Purchase by DME Supplier of Internet Leads," Medtrade (Feb. 9, 2015).

The Jig is Up: Florida Combats Patient Brokering through New Legislation

By: Sam Winikoff

Floridians know well the devastation associated with America's opioid epidemic. According to the Florida Department of Law Enforcement, opioids were the cause, or present at the time, of death in 10,621 cases in 2016, an increase of 89.46% from 2012. But Floridians are less familiar with how the expansion of insurance coverage for behavioral health under the ACA and the Mental Health Parity and Addiction Equity Act (MHPAEA), though critical for effective treatment of opioid and other substance use disorders (SUDs), has led to the proliferation of unscrupulous treatment and recovery residence providers. In response, the Florida Legislature appropriated funds to the State Attorney's Office for the Fifteenth Judicial Circuit, led by Dave Aronberg, to create what has been termed the "Sober Homes Task Force." The Task Force is a body of elected officials, civic leaders, industry providers, and health care attorneys, charged with further uncovering these exploitive practices and making specific recommendations to move SUD health care in Florida towards transparency and ethical behavior through new legislation and a stronger regulatory framework.

In its 2017 report, the Task Force identified that patient brokering, as addressed in the Patient Brokering Act, § 817.505, *Florida Statutes* (the "PBA"), was prevalent among industry abuses, and most often when in connection with illegal referrals from recovery residences that served not as homes of respite, but rather as warehouses of patients. State Attorney Aronberg convened the Palm Beach County Grand Jury in 2016 to investigate these issues and found that, when patients, and particularly those from out-of-state, transition from an inpatient level of care to an outpatient level of care, they were regularly unable to identify a safe and affordable sober living environment to continue their recovery. As insurance providers continue to consider post-inpatient housing to be medically unnecessary, patients changing levels of care often need some form of financial assistance for their housing needs. And often, this leads the unscrupulous treatment provider to pay for the resident's housing costs in exchange for a referral from the housing provider to their facility, or patronage by the patient him or herself.

The Grand Jury and the Task Force reports both made specific policy recommendations to the Legislature to address these issues, most of which were implemented by HB 807 (2017). Prior to HB 807's adoption, the PBA made it unlawful for any treatment facility to "offer or pay any commission, bonus, rebate, kickback, or bribe, or engage in any split-fee arrangement" to induce the referral of patients. The law now also includes in its prohibitions the solicitation or receipt of any "benefit." HB 807 also created enhanced penalties based upon the number of patients involved in the prohibited conduct, ranging from a third degree felony up to a first degree felony.

In addition to enhanced penalties for patient brokering violations, HB 807 added § 397.4873, *Florida Statutes*, to govern referrals to or from recovery residences. Now, a licensed treatment provider may not make a referral of a prospective, current, or discharged patient to, or accept a referral of such a patient from, a recovery residence unless the recovery residence holds a valid certificate of compliance as provided for in Section 397.487, *Florida Statutes*. The recovery residence must also be actively managed by a certified recovery residence administrator ("CRRA") as provided for in Section 397.4871, *Florida Statutes*. The certificate of compliance is issued by FARR, the Florida Association of Recovery Residences, and certification of the CRRA is credentialed through the Florida Certification Board. The bill also removed the exemption for referrals to a recovery residence owned and operated by a licensed treatment provider (or its wholly owned subsidiary) on or after July 1, 2018. Finally, after June 30, 2019, the State will be able to impose administrative fines of $1,000 for violations of Section 397.4873. It will also be able to either suspend or revoke licensure in cases of repeat violations.

These legislative accomplishments have put Florida at the forefront of the country's fight against the opioid epidemic. The State is now recognized nationally for its implementation of some of the country's most comprehensive reforms to combat the epidemic and address patient brokering targeted at those seeking recovery from SUDs. In Palm Beach County, there have been 56 arrests utilizing the PBA, which have led to 26 patient brokering convictions. Increased availability of Narcan (an antidote to opioid overdoses), interdictions of fentanyl and carfentanil, in addition to efforts at all local levels, have also made a significant impact. Though not yet conclusive, overdose rates in Palm Beach County are projected by the Medical Examiner to decrease by nearly 40 percent in 2018.

Sam Winikoff is an associate at Beighley, Myrick, Udell, & Lynne, P.A., with offices in Boca Raton, Pompano Beach, and Miami. His practice focuses on health care transactions and regulatory compliance with a specific emphasis on substance use disorder (SUD) treatment facilities, behavioral health care programs, and recovery residence providers.

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