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INSIDE:

Chair's Message

Spring Renewal and Addressing Stress

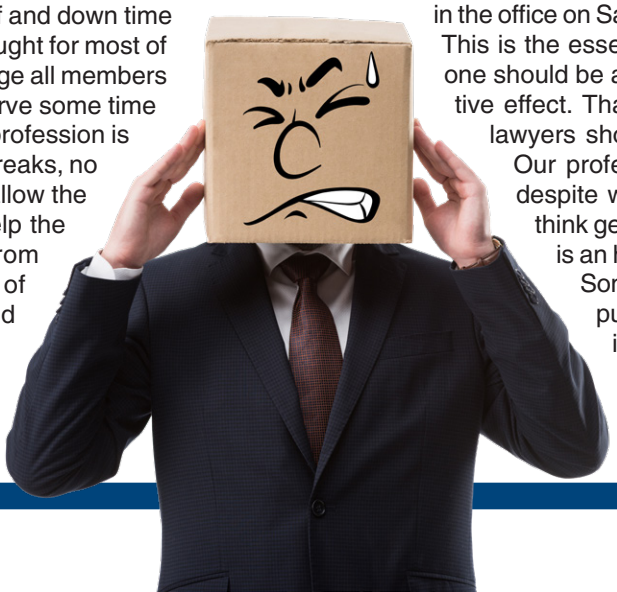
By: Gregory A. Chaires

While it is March already, Happy New Year to you all! Hopefully your New Year's resolutions have had some staying power for you during the first couple of months of the year. If not, the good news is that you can always set new goals and take baby steps to accomplish them. Resolutions can be let-downs that ultimately make you feel like you have failed. I see resolutions as promises to yourself and goals as targets you set to achieve. I think taking baby steps is the best way to achieve goals.

As we approach the time period where many of our children have spring break, it is important to keep in mind that lawyers need breaks as well. It is important for all of us to de-stress, re-charge and seek renewal. A lawyer's mind rarely turns off and down time is just a fleeting thought for most of us. I would encourage all members of the Section to carve some time out to do that. Our profession is prone to burnout. Breaks, no matter how small, allow the brain to refocus, help the body recalibrate from the natural stress of being a lawyer, and ultimately permit us to be more productive. Those breaks do not have to be a vacation, and can include hobbies, time with loved ones, participating in volunteer work that has nothing to with the law, or even sightseeing.

There are many derivatives of the old phrase "All work and no play," but the one I like is "All work and no play is not good for the soul."

Let's face it - practicing law is stressful and if you do not take breaks, that stress can be cumulative and lead to serious health issues. Lawyers can suffer from depression, anxiety, poor eating and sleeping habits, the feelings of being overwhelmed, high blood pressure, high cholesterol and a host of other health conditions. Feeling such stress can lead to forgetfulness, irritability and intolerance, and affect our relationships by causing us to withdraw from friends and family. Some law firms encourage working every weekend and do "cell" checks to see which lawyers are giving "facetime" in the office on Saturday and Sunday. This is the essence of burnout and one should be aware of its cumulative effect. That is not to say that lawyers should not work hard. Our profession is noble and despite what the public may think generally of lawyers, it is an honor to help others. Sometimes you have to put in the long hours, it just should not be all the time. Down-time is good for



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CHAIR'S MESSAGE

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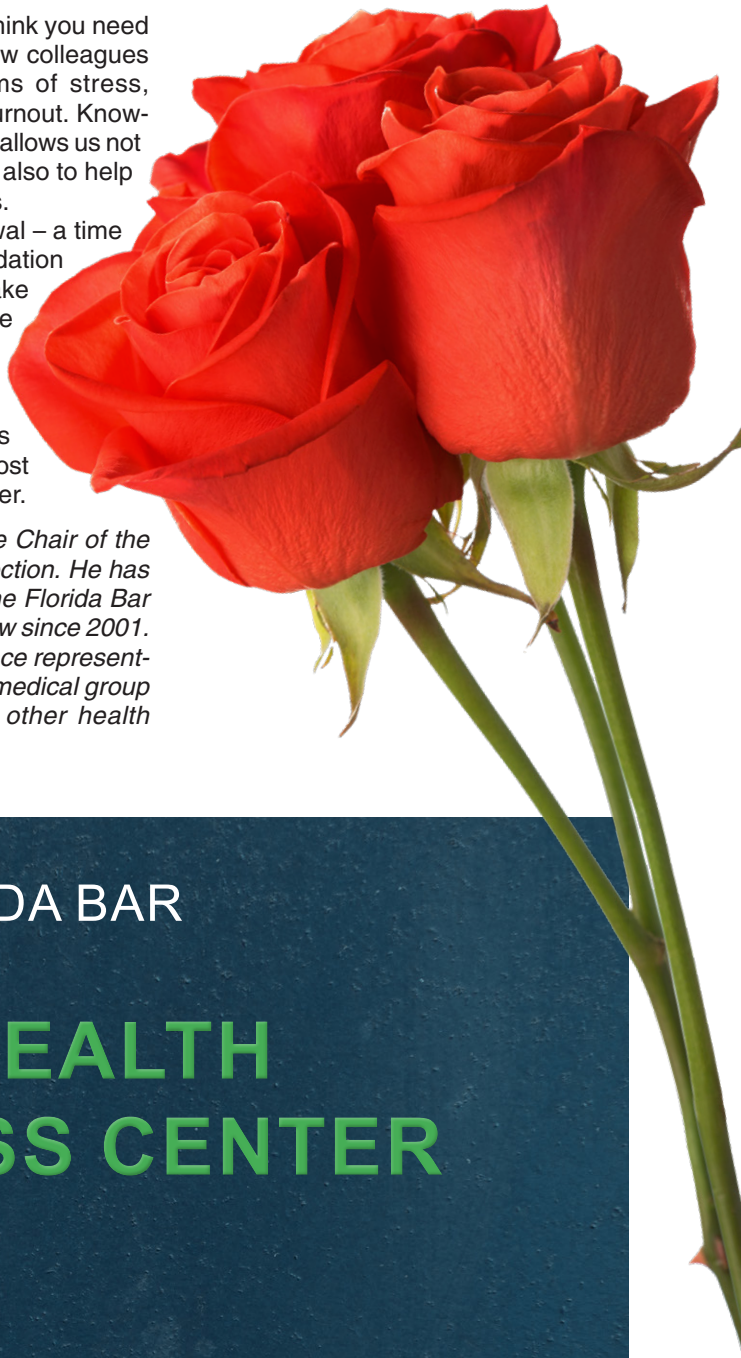
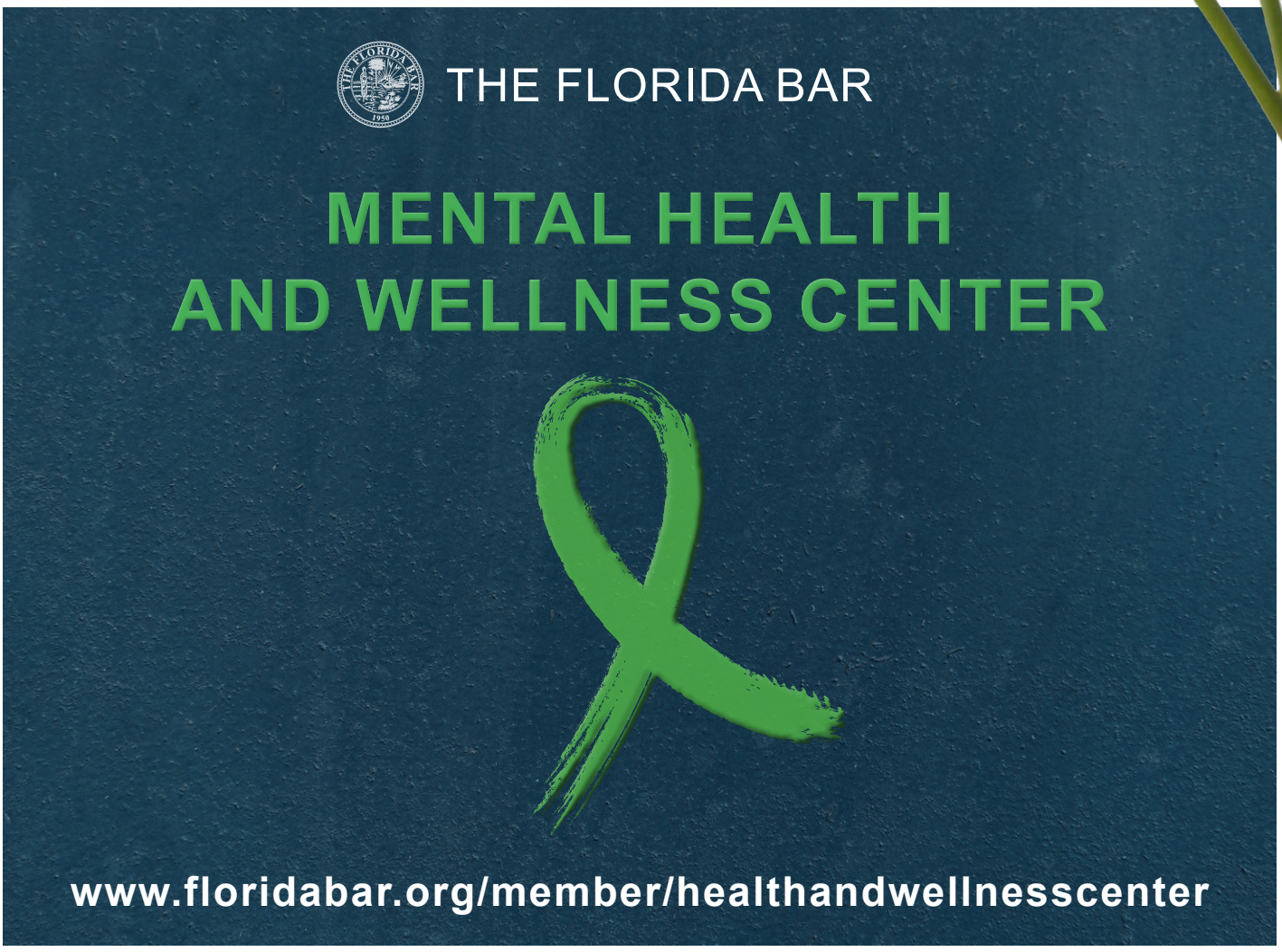
all. Machines overheat and break when pushed excessively - humans do too.

For those of you that feel you may have crossed over the threshold of burnout, or are feeling depressed, overwhelmed, unable to focus, anxious, or just plain irritable, the Bar has resources to help you. Not your favorite watering hole, but the Florida Bar. I would encourage all Section members to spend a couple of minutes looking at the Health and Wellness Center on the Florida Bar's website at https://www.floridabar.org/member/healthandwellnesscenter/. You will find lots of resources available, including access to well-being coaches, informative articles and kits focusing on how to deal with stress, as well as the ABA Well-Being tool kit. There are also several free CLE videos that allow you to "fill two deeds with one need" as you will gain information and also obtain CLE credit. Even if you do not think you need to review them, we all know colleagues that suffer from symptoms of stress, anxiety, depression and burnout. Knowing the available resources allows us not just to help our clients, but also to help our friends and loved ones.

Spring is a time of renewal – a time to refocus and lay the foundation to be more productive. Take some time off and smell the roses. You will enjoy what you do more, embrace life more and value those around you more. May this renewal lead you to your most fulfilling year yet as a lawyer.



Gregory A. Chaires *is the Chair of the Florida Bar Health Law Section. He has been Board Certified by the Florida Bar as a specialist in Health Law since 2001. He has extensive experience representing health care providers, medical group practices, hospitals, and other health care facilities.*



– Getting to Know –

Adam Maingot

Health Law Section Member Spotlight

Adam Maingot is the Secretary of the Florida Bar Health Law Section. He is a Senior Healthcare Attorney with Publix Super Markets, Inc., where he has worked in the Corporate Counsel's office for over three years. Prior to becoming an attorney, he worked in the healthcare industry as director for Florida's largest orthopedic group, a senior consultant at a multinational business consulting firm, and at a health insurance company. He obtained his J.D. at Stetson University College of Law, where he graduated second in his class.

Please tell us what made you want to become a lawyer.

I really enjoy researching the law, coming up with creative solutions, and helping others.

You had significant experience in the private sector prior to going to law school. How have those experiences affected how you advise your client?

I think my private sector experience makes me much more relatable to my colleagues at my company because I understand their business needs. I also understand the reason why simply saying "no" is not an acceptable answer!

What made you want to get involved in the Health Law Section?

I felt the Florida Bar Health Law Section was the best way to connect with my peers in the area in which I practice. I love being in Florida, and the Section lets me meet attorneys in my state who do the type of work that I do.

What was your path to leadership in the Florida Bar Health Law Section?

Ninety percent of the job is just showing up. Not everyone comes to the Section meetings and participates, so if you're a person who has drive and initiative and shows up, you're going to get asked to do things. I leaned in and participated, which is how I got to my current position in the Section.

What advice would you have for lawyers looking to get more involved in the Health Law Section?

Come to Health Law Section meetings and make your voice heard. Provide meaningful contributions.

You have worked both in a law firm and in-house setting. What advice do you have for lawyers thinking about going in-house?

Keep your advice short and to the point. Provide actionable feedback. You don't always have to show your math, so to speak. A big, fancy memo is often unnecessary. If you have to give a "no" answer, provide useful alternatives to get the client where they need to go.

What qualities do you most appreciate in outside counsel?

You need someone who is direct, concise, and who will be your advocate. You need someone who is willing to jump in the ring with you if the answer is a tough one. Sometimes you're looking for a second set of eyes to confirm your thoughts. You also must be willing to be available. We're all busy, but the people with whom I have the best relationships are the people who answer my calls quickly and are responsive.

What do you like best about being a health lawyer?

Health law is challenging and engaging for me. It's not an easy practice area, but the facts are always really interesting and complex, which keeps me engaged. I spend most of my time as a pharmacy attorney. I get to handle amazing, complicated issues and I like it a lot.

What is on your bucket list?

I'd like to travel around the world with my kids someday.

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This article is part of a series of interviews highlighting members of the Florida Bar Health Law Section. Please contact the editor, Shannon B. Hartsfield at shannon.hartsfield@hklaw.com to recommend someone we should feature in a future edition. Ms. Hartsfield is Board Certified in Health Law by the Florida Bar Board of Legal Specialization and Education, and she practices at Holland & Knight LLP.

Empowering Patients to Conquer Medical Bills

By: Maria T. Santi

Patients, whether insured or uninsured, often face expected and unexpected medical bills from hospitals, medical facilities and healthcare providers. While patients and consumers have a choice as to their health plan, they do not have a say in the contracts between health insurers, hospitals and healthcare providers. This is important because health insurers negotiate contract rates for medical services on behalf of patients. Providers will then bill for services at their standard rates and charge the remainder to patients as part of the co-pay, deductible or remaining balance. This structure leaves patients in the dark related to the medical costs they must bear or not bear. The most common types of health insurance plans are HMOs, PPOs and POS plans. In 2017, employer-based health insurance was the most common, covering 56% of the population for some or all of the calendar year, followed by Medicaid 19.3%, Medicare 17.2%, direct-purchase coverage 16.0%, and military coverage 4.8%. Florida patients have rights and remedies guaranteed by statute when medical billing issues arise, especially when emergency medical services are rendered. This article will discuss patient rights and remedies under Florida law related to medical bills.

A. Transparency of Medical Bills

Patients and providers should be aware that Florida law requires transparency when it comes to medical bills. The Florida Patient Bill of Rights and Responsibilities under Section 381.026, *Florida Statutes*, states that patients are entitled to receive itemized billing information when requested, along with an explanation of any charges. This section applies to hospitals, ambulatory surgical centers, medical doctors, osteopathic physicians, podiatric physicians, nurse practitioners and hospice service providers. Sections 458.323 and 459.012, *Florida Statutes*, require that a patient receive itemized billing information from medical doctors and osteopathic physicians. The law specifically states that, whenever a licensed physician renders professional services to a patient, the physician is required, upon request, to submit to the patient, the patient's insurer, or any state or federal administrative agency under which the patient is entitled to benefits, an itemized statement of the specific services rendered and the charge for each. A physician may not condition the furnishing of an itemized statement upon prior payment of the bill.

Likewise, section 395.301(1)(d)(1), *Florida Statutes*, requires hospitals to provide itemized billing information to patients. The information must be provided within seven days after the patient's discharge or release or after a request for such statement or bill, whichever is later. The initial statement or bill must contain a statement of specific services and expenses incurred by date and provider for such items of service, enumerating in detail the services received within each department of the licensed facility and including unit price data on rates charged by the licensed facility. The statement or bill must also clearly identify any facility fee and explain the purpose of the fee, identify each item as paid, pending payment by a third party, or pending payment by the patient, and must include the amount due with a due date. The initial statement or bill must also direct the patient to contact the patient's insurer or health maintenance organization regarding the patient's cost-sharing responsibilities. Chapter 395, *Florida Statutes*, also requires hospitals to provide estimates to patients upon request prior to the provision of medical services.

Once patients receive the required information, they can properly evaluate the costs of medical services charged. The first step is to determine the patient responsibility based upon the insurance contract. Once this is done, patients must then evaluate charges to determine if they are reasonable. Under Florida law, medical bills are considered offers, not obligations to pay. See A.J. v. State, 677 So.2d 935, 937 (4th DCA 1996). This allows patients to make counter offers when they receive a medical bill and to engage in negotiations. Furthermore, patients are only required to pay the reasonable amount of services provided by healthcare professionals. The reasonable amount is determined by comparing the charges with all charges for the specific procedure in the geographic area. Medical coding and audits can help patients determine the actual reasonable charges to be paid.

B. Billing Medicare Patients

Medicare recipients are entitled to certain protections by law. Pursuant to Section 456.056 (3), *Florida Statutes*, if treatment is provided to a Medicare beneficiary for an emergency medical condition as defined in Section 395.002(8)(a), *Florida Statutes*, the physician must accept Medicare assignment, provided that the requirement to accept Medicare assignment for an emergency medical condition shall not apply to treatment rendered after the patient is stabilized, or if the treatment is unrelated to the original emergency medical condition.

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This newsletter is prepared and published by the Health Law Section of The Florida Bar.

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EMPOWERING PATIENTS

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Section 456.056(5), *Florida Statutes*, further states that "[a]ny attempt by a primary physician or a consulting physician to collect from a Medicare beneficiary any amount of charges for medical services in excess of those authorized under this section, other than the unmet deductible and the 20 percent of charges that Medicare does not pay, shall be deemed null, void, and of no merit."

C. Billing HMO Patients

Section 641.31, *Florida Statutes*, governs HMO contracts. Every HMO contract must state that emergency services and care shall be provided to subscribers in emergency situations not permitting treatment through the health maintenance organization's providers, without prior notification to and approval of the organization. See §641.31(12), Fla. Stat. In this situation, the HMO must pay not less than 75 percent of the reasonable charges for covered services and supplies, up to the subscriber contract benefit limits. Payment may be subject to applicable copayment provisions, not to exceed $100 per claim. Patients should also be aware that some insurance contracts, mainly HMO contracts, do not allow providers to balance bill patients, meaning that after the insurance pays, the provider cannot recover more than the copay and deductible from the patient.

D. Balance Billing Patients by Out of Network Provider

A health insurer is solely liable for payment of fees to a nonparticipating provider of covered emergency services provided to an insured patient in accordance with the coverage terms of the patient's health insurance policy. See §627.64194(2), Fla. Stat. If a patient receives emergency services by an out of network provider, the patient is not liable for payment of fees for covered services to a nonparticipating provider of emergency services, other than applicable copayments, coinsurance, and deductibles. Furthermore, if a patient receives non-emergency medical services from a health care provider who is out of network, but provides medical services in a facility that is in network, a patient is not liable for payment of fees to the non-participating provider, other than applicable copayments, coinsurance, and deductibles. Nor is the patient liable when he or she does not have the ability and opportunity to choose a participating provider at the facility who is available to treat the insured. The patient's insurance company is solely liable for payment of fees to the non-participating provider. See §627.64194(3), Fla. Stat.

E. Remedies

The patient bill of rights makes clear that the disclosure of financial information and itemized billing information from healthcare professionals is required, yet there is no mechanism to bring legal action under the Patient Bill of Rights for a violation. However, there are other legal theories allowing patients to bring actions related to violation of their rights when there are inappropriate billing practices related to medical charges. First, if a facility or healthcare provider fails to provide the requested information, a patient can initiate legal action to the extent damages resulted from the non-disclosure of billing information. Second, when a bill is sent to a third-party collection agency by a healthcare provider or facility for a balance not owed, or for unreasonable charges, the patient may bring an action under the Fair Debt Collection Practices Act. This may result in strict liability against the collection agency for billing patients inappropriately. Third, the same type of inappropriate billing practices can give rise to a cause of action under the Florida Deceptive and Unfair Trade Practices Act when healthcare providers and collection agencies bill patients for charges they are not responsible for and/or induce patients to pay for bills that are inflated and superfluous. Lastly, when hospitals induce patients to pay for charges that are above the reasonable amount, patients may have a cause of action under fraud in the inducement for the hospital's misrepresentation of the reasonable charge. Patients should dispute medical bills upon receipt, and not later than 30 days from receipt, to reserve their rights to bring legal action for any disputes that may arise. Uninsured patients need to focus on the reasonableness of any charges while insured patients need to focus first on the structure and requirements of the insurance policy, and second, the reasonableness of the charges. Transparency of medical bills is a challenge that can be overcome by the laws enunciated for Florida's patients.

Maria T. Santi *is the founder and Managing Attorney of the Health and Medicine Law Firm in Coral Gables, FL. She represents patients throughout Florida in medical bill disputes, health insurance appeals, and civil actions against health insurers, medical and elder facilities, and medical professionals when patient rights are violated.*

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Did You Know? Two Very Different Florida "Clinic" Licenses

By: Shannon B. Hartsfield

Florida health lawyers need to be aware of two separate health clinic licenses that some clients will need. These permits are issued by two different state agencies, for different purposes.

Health Care Clinics

AHCA issues licenses for health care clinics pursuant to the Health Care Clinic Act, found in Part X of Chapter 400. The goal behind the creation of the law was to strengthen clinic regulation to "prevent significant cost and harm to consumers." A "clinic" is defined in Section 400.9905, *Florida Statutes*, as an entity that provides health care services to individuals "and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider." In "frequently asked questions" on its website, AHCA defines a health care clinic as "an entity that provides health care services and bills third party payors (i.e. Medicare, Medicaid, Private Insurance). If your facility meets this complete definition, then your facility is a health care clinic." Separate locations require separate licenses, and must have a medical director or clinic director who performs the functions set forth in Section 400.9935.

An extensive list of entities are exempt from the requirement to obtain a clinic license. These exemptions are listed in subsection 400.9905(4)(a)-(n). They include, among other things, entities that employ 50 or more licensed doctors and that bill under a single tax identification number. Entities owned by hospitals, certain charitable institutions, and a number of other types of organizations are also exempt.

Health Care Clinic Establishments

Even if an entity is exempt from the requirement to obtain a health care clinic license from AHCA, it may still need a different type of health care clinic permit. Specifically, the entity may need a health care clinic establishment permit from Florida's Division of Business and Professional Regulation ("DBPR"). Health care clinics must obtain a permit from DBPR's Division of Drugs, Devices and Cosmetics, pursuant to Section 499.01(2)(r), *Florida Statutes*, if they wish to purchase prescription drugs in the name of the entity. No permit is needed in order for a licensed practitioner to purchase drugs personally under the practitioner's name. In order for a business entity to purchase the drugs, however, the permit is required.

Although they have similar names, these two permits are very different. Florida health lawyers should examine carefully the purposes of these two separate licenses so they can advise their clients properly.

Shannon Britton Hartsfield *is a partner in Holland & Knight LLP's health law team. Her practice focuses on regulatory compliance for hospitals, long term care companies, pharmaceutical distributors, and other members of the health industry.*

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

Prescribing Controlled Substances via Telehealth under Florida and Federal law

By: Susan L. St. John

Pursuant to Section 456.44(3)(a), *Florida Statutes*, and Rule 64B8-9.013(3)(a), *Florida Administrative Code*, a practitioner must evaluate a patient by taking a complete medical history and performing a physical examination prior to prescribing a controlled substance to a patient. The aforementioned statute and rule do not specifically rule out a patient evaluation taking place via a telemedicine visit. However, under current Florida law, only controlled substances used to treat psychiatric disorders may be prescribed using telemedicine technology, that is audio and video technology commonly referred to as telepsychiatry. Specifically, Rule 64B8-9.0141(4) states, "[c]ontrolled substances shall not be prescribed through the use of telemedicine except for the treatment of psychiatric disorders." Psychiatric disorders include Substance Use Disorders since the DSM-V classifies addiction as a mental health condition. Although the Standards for Telemedicine Practice under Rule 64B-9.0141, *Florida Administrative Code*, allows licensed practitioners to prescribe controlled substances for psychiatric disorders via telehealth technology, the federal law has lagged somewhat behind.

The federal Controlled Substances Act requires a practitioner to register to prescribe controlled substances via telehealth. This special registration was intended to increase patients' access to practitioners who can prescribe controlled substances via telemedicine in limited circumstances. In order to be able to prescribe controlled substances under the special registration, a practitioner must (1) demonstrate a legitimate need for the special registration, (2) be registered to deliver, distribute, dispense, or prescribe controlled substances in the state the patient is located, and (3) the practitioner must maintain compliance with federal and state laws when delivering, distributing, dispensing, or prescribing controlled substances. Once registered, a practitioner would be allowed to deliver, distribute, dispense, or prescribe a controlled substance via telemedicine. Further, under the special registration, a practitioner would not need to examine a patient in person – a telemedicine encounter would be sufficient.[1]

Currently, practitioners have not been able to apply for the special registry under the Controlled Substances Act since the DEA has yet to promulgate the final rules for a registration's application process and procedures. However, this should change in the near future. On October 24, 2018, President Trump signed into law the SUPPORT for Patients and Communities Act ("SUPPORT Act") which mandates that the DEA's final rule for the special registration be in place within one year of the enactment of the SUPPORT Act.

Once the final rule for the special registry is promulgated, registration opens up, and a Florida practitioner obtains special registration, that practitioner should be able to prescribe controlled substances without an "in-person" face-to-face encounter. The practitioner should be able to prescribe controlled substances for psychiatric disorders via telemedicine technology (audio and video). However, keep in mind, a practitioner must still follow standards of care for his or her practice act including, but not limited to, obtaining previous medical records, preliminary and routine lab work (e.g., urine analysis) or other diagnostic studies to determine if the patient is or continues to be an appropriate candidate for a controlled substance prescription. To comply with Florida law a practitioner prescribing controlled substances will need to adhere to Section 456.44, *Florida Statutes*, Controlled Substance Prescribing, and Rule 64B8-9.013, *Florida Administrative Code*, Standards for the Use of Controlled Substances for the Treatment of Pain. When treating patients with controlled substances via telemedicine, careful planning will need to be implemented in order to obtain lab results, other diagnostic tests, or other practitioners' medical records ahead of scheduled telemedicine encounters.

1. Congressional Research Service, The Special Registration for Telemedicine: In Brief, Updated December 7, 2018.

Susan L. St. John *is an attorney with the Florida Healthcare Law Firm in Delray Beach. Her practice focuses on health law, tax law, estate planning, business planning and civil trial law.*

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GDPR: HIPAA Compliance May Not be Enough

By: James F. Bush

Florida-based health and life science organizations that process European Union citizens' personal data are now, with very limited exception, subject to the EU's General Data Protection Regulation ("GDPR"). On May 25, 2019, GDPR will reach its first anniversary in force. The EU first adopted the privacy regime in April 2016 and, while non-compliance penalties can be severe, the Economist estimates 60% of covered organizations were "not ready" to attain compliance with GDPR the day it went into effect. With the growth of international clinical research, device and drug manufacturers, contract research organizations, and academic institutions that coordinate international, multi-center clinical trials are increasingly prone to processing EU citizens' personal data. Currently, over 1,800 active clinical trials registered with the NIH and FDA have sites located both within Florida and the EU. Further, GDPR has also come to serve as a benchmark for both new U.S.-based legislative efforts—such as California's Consumer Privacy Act (CCPA)—and for insurance products covering cyber liability. Thus, understating the purpose, reach, and effect of GDPR has become a major compliance consideration for health researchers and their legal counsel.

The goals of GDPR were threefold: 1) enhanced protection of EU citizens' data, 2) harmonization of EU data privacy laws, and 3) expanded and more stringent enforcement. Covered "personal data" includes any information collected that could directly or indirectly identify an EU citizen. Such data points include names, photographs, e-mail addresses, banking information, social networking posts, IP addresses and, of course, health, genetic, and biometric information. GDPR's reach extends to all foreign companies that "offer goods or services to, or monitor the behavior of, EU data subjects," regardless of whether the company or the data physically reside within the EU. Non-EU companies engaging in "large-scale" processing of personal data may be required to appoint an internal Data Protection Officer and/or an external compliance representative inside the EU.

GDPR sets out several significant data subject autonomy rights. These include data subjects' rights to fully access, delete, and receive copies of the data retained about them. Further, organizational and technical privacy measures (such as data breach policies and encryption) are required by default. Like HIPAA, data controllers must observe "minimum necessary" and "as-needed" access principles. GDPR treats health, biometric, and genetic information as especially sensitive and organizations that wish to process *any* sensitive personal data must, with limited exception, obtain clear and unambiguous consent to do so from subjects.

On the enforcement side, U.S.-based organizations face the same penalties for non-compliance as their EU counterparts. A serious breach of GDPR's mandates—such as a violation rules pertaining to subject consent—warrants maximum fines as high as the greater of 4% of annual revenue or approximately $25 million USD. A system of graduated penalties exists for less serious infractions.

For U.S.-based health organizations, the most meaningful comparison that can be drawn to GDPR is with HIPAA. While organizations used to dealing with PHI may be well positioned to lead GDPR compliance efforts, HIPAA compliance is not enough. For example, the simple act of transferring personal data from the EU to the U.S. is particularly fraught. In the landmark 2015 case of *Schrems v. Data Protection Commnr.*, the European Court of Justice, in assessing data security in the post-Snowden era, deemed data transfers to the U.S. as being particularly susceptible to a risk of "unlawful access" by the U.S. government. While HIPAA-compliant organizations have a good leg up in GDPR compliance, attainable changes in organizational policies, processes, and safeguards are still required. Ultimately, GDPR will likely represent the framework from which US lawmakers look for future legislation. Even organizations that do not currently process EU citizens' personal data might do well to understand GDPR as a reference point for internal privacy efforts.

James F. Bush *is an attorney with Dell Graham, P.A. in Gainesville, representing clients in health law, commercial and civil litigation matters. He is a graduate of the University of Florida (B.A. '06) and Stetson University (J.D. '09).*