THE FLORIDA BAR

Health Law Section Newsletter

THE RESOURCE FOR FLORIDA HEALTH LAW

The Florida Bar Health Law Section

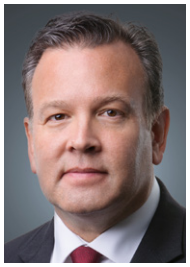
Vol. XVII, No. 18 www.flabarhls.org Fall 2019

INSIDE:

Chair's Message

Goals For The Upcoming Term…

By: Everett Wilson



It is my honor to serve as Chair of the Section for the upcoming term. Our goal for the year can best be summed up by a simple statement – to permanently improve the value of the Section to our members.

We are fortunate in that a strong foundation has already been laid by prior leadership and all those members of the Section who have volunteered their time to further the Section's initiatives and programs. We are thankful for their efforts and the lasting impact they have made upon the Section. More importantly, though, they have set an example for our more recent members on what can be accomplished when diversely minded individuals with different skill sets are able to rally around issues of common interest to our collective membership. As we see newer members continuing to volunteer their time, I recognize that this is their true legacy.

In addressing how we will go about accomplishing our goal of improving value, allow me to summarize our current state of affairs. We are an "industry" focused Section comprised of practitioners of all types – regulatory, litigation, corporate, criminal, administrative, employment, tax, etc. The common denominator is that we service clients in the health care or health care insurance industry or are otherwise impacted by the same – an industry which represents almost 20% of the U.S. economy and employs one in every 8 individuals in the U.S. It is an industry comprised of many sectors and, thus, our respective clients and the matters we assist them with are varied in type, size, and complexity.

Our clients (and we by extension), in turn, also share something in common. They operate in a highly regulated environment – which regulations impact almost every facet of their professions and businesses. More importantly, though, those government regulations and initiatives actually drive our clients' business models and are the cause of not just constant change, but opportunity. Further compounding the effect of new regulations, is that health care is ever changing. The evolution of technology, biological advances, and even changes in societal norms, far outpace the passage of laws and regulations. Thus, we are sometimes called upon to advise clients on scenarios for which existing laws provide inadequate guidance.

What all of this means is that in order for the Section to improve value for its members, it must go beyond its position of being the go-to source in Florida for CLE in health care law. The modern health care lawyer and our other members require more from their Section.

That being said, the Section will continue to offer first rate educational programs, but with a renewed and deliberate intent towards incorporating the latest trends in law and industry. Further, the Section will strive to make our programs more accessible to all of our members – both through geographic diversity of our in-person events and through technology and other media.

This term, the Section will also focus on professional and practice development for the benefit of our members. This will be

continued, next page

CHAIR'S MESSAGE

from previous page

accomplished through more local and state-wide networking events and other opportunities for engagement amongst Section members. This includes taking affirmative steps towards the creation of a communication platform for the exchange of thoughts, information, and business opportunities. Because of the diversity of our varying practices, we will likely learn more from each other than from any CLE event we may attend. That same diversity of practices also creates an environment for the exchange of opportunities and for business development and referrals amongst our members.

Further, since the value of a group may also be measured by what the group can accomplish collectively versus individually, you can look to the Section to take a more active role on issues that impact us collectively, particularly where the Section may be in the best position to advance those interests. In that regard, the Section will continue to monitor legislative issues. However, we encourage all of our members to engage with the Section so as to keep the rest of the Section's members informed as to other legal and industry issues as they encounter them.

The point cannot be stressed enough, though, that we need and are actively seeking the involvement of all of our members to advance these value enhancing initiatives. Thus, I encourage all of our members to keep abreast of our emails, website, and to follow our new LinkedIn page www.linkedin.com/company/health-law-section-of-the-florida-bar and to participate and engage with the Section and its other members. I would also encourage all members to please feel free to reach out to me or Emily Young, the Section's program administrator, with any suggestions or other input on how the Section can best serve you.

I can be reached at everett.wilson@polsinelli.com. Emily may be reached at eyoung@floridabar.org.

We are looking forward to a great year.

Compounding Medications for Office Use

By: Deirdre Boling-Lewis

Medication compounding is the process of combining individual ingredients to create a customized medication for those segments of the population for which a commercially available product does not work. Commercially available products are manufactured drugs for which the FDA has reviewed filings from the application sponsor that have been prepared by or on behalf of the drug manufacturer. These filings relate to the safety and efficacy of the proposed drug. During the review of these filings, the FDA determines the benefits as compared to the known risks of the proposed drug's intended use. Commercially available products may contain certain ingredients, like preservatives, to which patients may be allergic or sensitive. Or sometimes, the patient simply needs the commercially available drug in a different form or strength - for example, a cream for topical administration rather than a tablet or capsule or an ingredient at 7.5% potency rather than 5%. In those situations, many physicians prefer to keep prescription medications on-hand for office use. But from where does that compounded medication come?

Obtaining Compounded Medications

Traditionally, prescriptions for compounded medications would be sent to compounding pharmacies on a patient-by-patient basis. However, in 2013, with the enactment of the Compounding Quality Act (Title I of the Drug Quality and Security Act, Pub. L. 113-54), Congress established a new section of the Federal Food, Drug and Cosmetic Act (FFDCA), Section 503B, thereby creating a new entity called an "outsourcing facility." Outsourcing facilities are a hybrid between a drug manufacturer and a traditional compounding pharmacy and are permitted to compound large quantities of medications. Like drug manufacturers, outsourcing facilities are required to comply with good manufacturing practices set out in 21 CFR Parts 210 and 211 (cGMP); unlike traditional compounding pharmacies, a patient-specific prescription is not required before an outsourcing facility can distribute the compounded medications to healthcare practioners and facilities. "Under Section 503B, outsourcing facilities are permitted to compound medications in large quantities and without the patient-specific prescription prerequisite," states Lee Rosebush, Chairman of the Outsourcing Facilities Association. "Outsourcing facilities, therefore, create a pathway for physicians to obtain as office stock compounded medications." Because outsourcing facilities are subject to cGMP requirements and the FDA inspections, as well as specific adverse event reporting requirements "and other conditions that provide greater assurance of the quality of their compounded drug products, . . . outsourcing facilities can compound and distribute sterile and non-sterile non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use." (*"Prescription Requirement"* Guidance, page 14)

Traditional Compounding Pharmacies & the Patient-Specific Prescription Requirement

In contrast, federal law expressly limits traditional compounding pharmacies to providing compounded medications only to specific, individually identified patients. Section 503A(a) of the FFDCA exempts traditional compounding pharmacies from compliance with certain provisions of the FFDCA (namely, compliance with good manufacturing practices, providing adequate directions for use on the label, and requiring that the medications compounded by FDA-approved) "if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or notation." Under federal law, a compounding pharmacy either may compound a medication after receiving a patient-specific prescription or may compound a medication in anticipation of receiving the patient-specific prescription, but not allow the medication to leave the compounding pharmacy until receipt of the patient-specific prescription. (See FFDCA Section 503A(a); *"State Oversight of Drug Compounding,' A Report*

continued, next page

COMPOUNDING MEDICATIONS
from previous page

from The Pew Charitable Trusts and the National Association of Boards of Pharmacy (February 2018) "Section 503A does not provide for distributing a compounded drug product before receiving a valid prescription order for an identified individual patient." ("*Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act,* page 8, Guidance for Industry (December 2016) at https://www.fda.gov/media/97347/download) "To meet the prescription requirement, a prescription must identify the patient for whom the drug has been prescribed. If the identity of the patient is not given or is not clear, it will not satisfy this requirement. For example, a prescription would not satisfy the requirement if it is written for the prescriber, when the prescriber is not also the patient." (*"Prescription Requirement"* Guidance, page 10-11) As such, compounding pharmacies are prohibited from compounding medications for "office stock."

Florida Law

In 2017, the Florida Board of Pharmacy revised Rule 64B16-27.700, *Florida Administrative Code,* to avoid "conflict with state and federal law and to make clear that office use compounding of products intended for human use (sterile and non-sterile) shall require being registered as an Outsourcing Facility," as defined by Section 465.003(19), *Florida Statutes.* (https://floridaspharmacy.gov/Meetings/Agendas/2017/12-december/12122017-ccagenda.pdf) As such, Rule 64B16-27.700, *Florida Administrative Code,* prohibits traditional compounding pharmacies not also registered with the FDA as an outsourcing facility from providing compounded medications as office stock.

Conclusion

Office stock plays a large role in patient care and with the ability to obtain from outsourcing facilities compounded medications that are customized to the needs of a certain segment of a practitioner's patients, the importance of access to compounded medication for use as office stock is sure to grow. However, it is important to understand from where compounded medications can be obtained without running afoul of state and federal law because compounding pharmacies found to be releasing medications compounded without first receiving a patient-specific prescription have been found to be in violation of the FFDCA. See https://www.fdanews.com/ext/resources/files/2018/2/10-04-18-InnovativeIntrathecalSolutions.pdf?1538681087; https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/custom-rx-llc-dba-custom-rx-pharmacy-and-wellness-concepts-559540-10182018; and https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/raniers-compounding-laboratory-521003-03282017) Failure to comply with this prohibition can result in permanent injunctions against the compounding pharmacy. (See https://www.fda.gov/news-events/press-announcements/federal-judge-enters-consent-decree-against-texas-compounder-guardian-pharmacy-services)

Deirdre Boling-Lewis *is General Counsel of Sincerus Pharmaceuticals, Inc. where she has broad responsibilities for the operation of the legal department, compliance, and government relations. Previously, Ms. Boling-Lewis was with Kaiser Foundation Health Plan, Inc, where she provided strategic leadership for Kaiser's national pharmacy program, and at Walmart Stores, Inc., where she spent 10-years in the Legal Department at Walmart Stores, Inc. in Bentonville, Arkansas, supporting Walmart's Health & Wellness division.*

– Getting to Know –
Eddie Williams
Health Law Section Member Spotlight

Eddie Williams III is a health law and tax partner in Holland & Knight's Tallahassee office. His practice focuses on healthcare regulation, state and local tax, cybersecurity and privacy. He is experienced in assisting clients with state and federal healthcare regulatory issues, particularly with respect to long term care, HIPAA, anti-kickback and patient self-referral laws. He also helps clients form nonprofit corporations. He has a law degree from Nova Southeastern University and an LL.M. in taxation from the University of Florida.

What made you decide to become an attorney*?*

During the summer months when I was growing up, two of my favorite television series were "Perry Mason" and "Matlock." From these shows, I became fascinated with the aspects of the legal system. As I grew older, I also had the privilege of admiring other attorneys in Albany, Georgia who were trailblazers in the legal industry. Such individuals include Sharon "Nyota" Tucker, who was my professor at Albany State University and was the first African American female to earn a Juris Doctorate degree from the University of Georgia School of Law, Chief Judge Herbert E. Phipps, Georgia Court of Appeals, Hon. Willie E. Lockett and Hon. Denise Marshall, Dougherty County Superior Court, Greg Edwards, Dougherty County District Attorney, and Atty. Johnnie Mae Graham just to name a few.

You started out as a tax attorney. What led you to health law?

It was just happenstance, I guess. As an associate, I started working with other attorneys who happen to focus their practices in health law. Over time, I began to focus and devote more time on health law. Both tax and health law are statutorily and regulatorily driven, but with their own unique complexities. For instance, in tax law, you could be assisting a client with how best to structure an acquisition transaction in order to obtain the best tax benefit. While in health law, you may have to advise a client on how to structure an arrangement to statutory and regulatory requirements in order to avoid the possibility of significant penalties.

What advice would you have for lawyers wanting to get into health law?

I would recommend that the lawyer speak with other lawyers who practice in the area of health law in order to learn if there is a certain subset of health law that the lawyer is interested in. Also, I would recommend that the lawyer attend a health law conference to learn more information about the area of law. Also, if the lawyer has the opportunity, he or she may want to try to work with another health law attorney, in the same firm for example, in order to develop an understanding of the unique issues that healthcare clients deal with on a day-to-day basis.

What do you like best about being a health lawyer?

I like being able to assist clients with working through issues they may be having with a regulatory agency. Not only does this give me the opportunity to help a client try to receive a favorable outcome, but it also allows me to build a rapport with individuals who work on behalf of local, state, and federal government. Such relationships can be very beneficial in your practice when trying to resolve problems or obtaining guidance on behalf of your clients regarding the application of the laws or rules.

What is your favorite type of work that you do?

I enjoy doing health care licensure work. I enjoy assisting and advising clients on the licensure requirements, any particular deadlines they must meet, and working through any survey issues that may be required in order to obtain the license. I also like performing the health care due diligence that is required in acquisition transactions.

What is it like to practice as part of a big firm?

Working at a big firm is very demanding, but also rewarding as it relates to assisting and advising clients. Specifically, if a client calls with an issue that I do not handle, you almost always can find an attorney within the firm who has the knowledge and skill set to help the client with the matter. Also, working at a big firm provides me with the opportunity to work with numerous other attorneys in other states.

If money were no object, what career would you have chosen besides being a lawyer?

I love sports, so I would have a career as a sports analyst. But that's not to say that sports analysts do not get paid well, because there are many in this field who are paid very well.

• • • •

This article is part of a series of interviews by Shannon Hartsfield highlighting members of the Florida Bar Health Law Section. 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.

Ectopic Pregnancy Misdiagnosis Can Lead to Harm from Methotrexate: Expert Witness Role

By: Gretchen Green, MD, MMS

Litigation may result from either failing to diagnose an ectopic pregnancy or treating a pregnancy as ectopic when it in fact was not ectopic. An obstetrical ultrasound expert witness may be called in such cases to opine on the standard of care and whether or not that standard was breached regarding the ectopic pregnancy imaging. Additionally, expert witnesses on quantitative β-hCG blood tests and methotrexate may also be called. The β-hCG and methotrexate causation expert witness may discuss whether treatments were appropriate and whether any treatment resulted in harm to the fetus.

What is an ectopic pregnancy?

An ectopic pregnancy is a pregnancy that develops in an abnormal location outside or within the uterus (womb). The incidence of ectopic pregnancy has been increasing over time, to a current estimate as high as 2% of all pregnancies.(1) Patients with a history of infertility treatment or prior ectopic pregnancy are at higher risk than the average woman.(2) Women with ectopic pregnancy risk bleeding and potential death due to hemorrhage (blood loss) if the abnormal pregnancy grows too large and tears surrounding tissue (rupture). Therefore, the goal is to diagnose ectopic pregnancy as early as possible, and with the greatest degree of accuracy.

How is ectopic pregnancy diagnosed?

Before the routine use of imaging exams such as ultrasound, ectopic pregnancy was diagnosed clinically and often only after rupture, necessitating emergency surgery and often with high mortality. Ultrasound can now be used to diagnose an intrauterine pregnancy as early as approximately five weeks gestational age, before a woman may even realize she is pregnant.

How can ultrasound diagnose ectopic pregnancy?

Ultrasound is a medical test using sound waves to image tissue noninvasively. The lack of radiation makes it popular in obstetrics to reduce the risk of exposure to both mother and fetus. As ultrasound resolution has improved, ultrasound has become better able to diagnose the different stages of early pregnancy, especially with transvaginal probes that are inserted into the vagina and provide a close-up view of the uterus and ovaries. A confident diagnosis of ectopic pregnancy can be made when a gestational sac, yolk sac, and fetal pole with cardiac activity are seen outside the normal location within the uterus, as in the ectopic pregnancy shown in Figure 1.

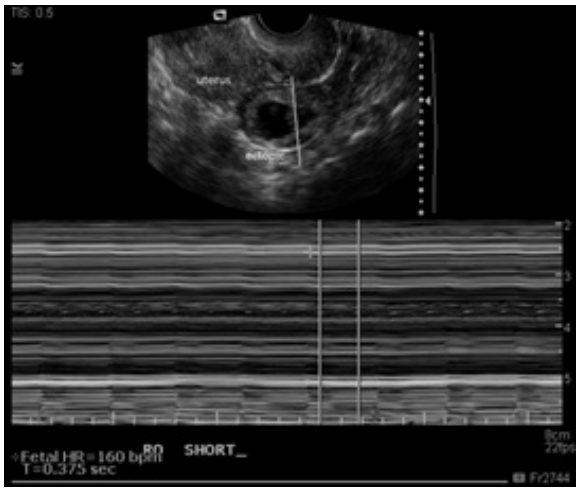


Figure 1: *Ultrasound image of right-sided ectopic pregnancy outside the uterus (labeled). The fetal pole (embryo) with cardiac activity (vertical lines indicating heart rate measurement in beats per minute) is visible.*

Visualization of a normal intrauterine pregnancy makes the diagnosis of ectopic pregnancy unlikely; ectopic pregnancy can coexist with an intrauterine pregnancy (termed heterotopic pregnancy) but this is rare.(3) However, the converse is not necessarily true; if neither an intrauterine nor ectopic pregnancy is seen at ultrasound, the risks and benefits of treatment for presumptive ectopic pregnancy should be considered before using medical treatment such as methotrexate.(4) The development of both normal pregnancies and ectopic pregnancy proceeds along a spectrum of findings at ultrasound, and diagnosis may not always be definitive based on the findings seen at the time of the exam.

What are the potential risks of litigation regarding ultrasound and ectopic pregnancies?

If no intrauterine pregnancy is seen

continued, next page

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

J. Everett Wilson.....Chair
JoAnn Guerrero.....Chair-Elect
Radha Bachman.....Secretary
Adam Maingot.....Treasurer
Gregory Chaires.....Immediate Past Chair
Shannon Hartsfield.....Editor
Emily Young.....Program Administrator
Clay Shaw.....Graphic Design/Layout

ECTOPIC PREGNANCY

from previous page

in a woman with a positive pregnancy test, diagnostic possibilities include normal intrauterine pregnancy too early to be seen, ectopic pregnancy, and miscarriage. (Figure 2)

If a woman is presumptively diagnosed with an ectopic pregnancy and given methotrexate, and is later found to have an intrauterine pregnancy instead, there is a risk of birth defects or miscarriage as side effects of methotrexate. If a quantitative β-hCG blood test is used to attempt to increase the sensitivity of diagnosis of ectopic pregnancy, correlation with ultrasound findings may help reduce the risk of misdiagnosis and potential harm to an intrauterine pregnancy.

Physicians interpreting ultrasound should be familiar with the development of normal and ectopic pregnancies as well as potential pitfalls in diagnosis.

Conclusion

An expert witness knowledgeable about the topic of ultrasound diagnosis of ectopic pregnancy may be a valuable resource to attorneys encountering cases of alleged missed diagnosis of ectopic pregnancy.

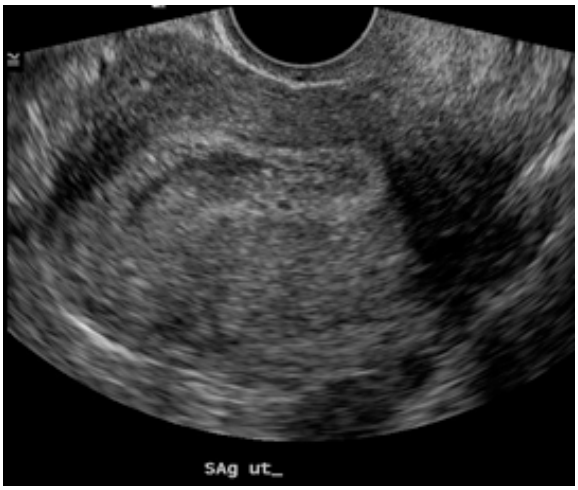


Figure 2: *No intrauterine pregnancy is visible in this patient; the location of the pregnancy is unknown. A surgically proven left-sided tubal ectopic pregnancy was later diagnosed.*

Gretchen Green, MD, MMS, drgreen@gretchengreenmd.com, *is a diagnostic radiologist in active clinical practice since 2006, who completed a fellowship in women's imaging including high-risk obstetrical ultrasound at Harvard's Brigham and Women's Hospital and a diagnostic radiology residency at Yale.*

Dr. Green is an affiliate member of the Florida Bar Health Law Section and has lectured nationally on diagnostic radiology topics and co-authored two breast imaging textbooks with colleagues at Harvard's Brigham and Women's Hospital.

References

1. Kao LY, Scheinfeld MH, Chernyak V, Rozenblit AM, Oh S, Dym RJ. Beyond ultrasound: CT and MRI of ectopic pregnancy. AJR American journal of roentgenology. 2014;202(4):904-11.

2. Levine D. Ectopic pregnancy. Radiology. 2007;245(2):385-97.

3. Dibble EH, Lourenco AP. Imaging Unusual Pregnancy Implantations: Rare Ectopic Pregnancies and More. AJR American journal of roentgenology. 2016;207(6):1380-92.

4. Doubilet PM, Benson CB. First, do no harm... To early pregnancies. Journal of ultrasound in medicine : official journal of the American Institute of Ultrasound in Medicine. 2010;29(5):685-9.

United States Supreme Court: Eighth Amendment's Excessive Fines Clause Applies to States

By: Tim Schoenwalder

In *Timbs v. Indiana*, 586 U.S. ___ (2019), the U.S. Supreme Court established that the Eighth Amendment's ban on excessive fines is an incorporated protection that applies to the states under the Fourteenth Amendment's Due Process Clause. While Timbs' underlying conduct violated state criminal laws, the Court's analysis and holding could portend added protection in Florida for health care entities and health care professionals should a state agency seek to impose excessive fines for non-criminal acts or omissions.

Timbs was arrested by Indiana police and charged with dealing in a controlled substance and conspiracy to commit theft. Police seized Timbs's Land Rover SUV which he had purchased using $42,000 received as a beneficiary under his deceased father's life insurance policy. Timbs pleaded guilty to the charges and was sentenced to one year of home detention plus various probation terms and the obligation to pay fees and costs totaling $1,203. Indiana brought a civil *in rem* forfeiture suit that targeted Timbs's Land Rover SUV, contending that he should forfeit the vehicle he used to transport heroin. While the state trial court found that Timbs had used the Land Rover SUV in connection with his violation of the criminal statute, that court determined, and the Indiana Court of Appeals subsequently affirmed, that the forfeiture "would be grossly disproportionate to the gravity of Timbs's offence, hence unconstitutional under the Eighth Amendment's Excessive Fines Clause."

The Indiana Supreme Court reversed the decision on appeal, but chose not to decide if the forfeiture was excessive, and instead categorically held that "the Excessive Fines Clause only constrains federal actions and is inapplicable to state impositions." Timbs appealed this decision to the U.S. Supreme Court ("USSC"), which granted *certiorari*.

Justice Ginsberg wrote the majority opinion. She traced the lineage of the Excessive Fines Clause back to the Magna Carta, and then to 1791 when the ratification of the first ten amendments to the U.S. Constitution applied this "Bill of Rights" solely to the federal government. After the Civil War, the Fourteenth Amendment was adopted and its Section 1 prohibits the states from, *inter alia*, depriving citizens of the United States of life, liberty and property without due process of law (the Due Process Clause). Thereafter, USSC precedent increasingly applied the Bill of Rights to the states, whether the constitutional amendment in issue prohibited or required state conduct. While the USSC on several occasions invoked the Due Process Clause to apply the Eighth Amendment to prohibit states from imposing excessive bail or cruel and unusual punishments upon U.S. citizens, the USSC prior to Timbs had left unresolved the Eighth Amendment's applicability to state actions under the Excessive Fines Clause.

Indiana argued that the Excessive Fines Clause did not apply because that clause's specific application in *Timbs* – to a civil *in rem* forfeiture proceeding – was "neither fundamental nor deeply rooted." The USSC declined to review the "fundamental" argument because it was not properly before the USSC. The USSC also declined to reconsider its prior unanimous judgment regarding federal forfeiture proceedings in *Austin v. United States*, 509 U.S. 602 (1993), that recognized "civil *in rem* forfeitures are fines for purposes of the Eighth Amendment when they are at least partially punitive." Justice Ginsberg explained that the standard inquiry must be to discern if the "Fourteenth Amendment incorporates a protection contained in the Bill of Rights" by asking "whether the right guaranteed – not each and every particular application of that right – is fundamental or deeply rooted." The Court essentially determined that the Eighth Amendment's Excessive Fines Clause is an incorporated protection that applies whenever a state seeks to apply an excessive fine which is "at least partially punitive."

Justice Ginsberg drew support for her analysis from several points which the late Justice Scalia offered when describing the relationship between states and fines in *Harmelin v. Michigan*, 501 U.S. 957 (1991)("Even absent a political

continued, next page

EXCESSIVE FINES CLAUSE

from previous page

motive, fines may be employed in 'a measure out of accord with the penal goals of retribution and deterrence,' for 'fines are a source of revenue,' while other forms of punishment 'cost a State money.'")("[I]t makes sense to scrutinize governmental actions more closely when the State stands to benefit.").

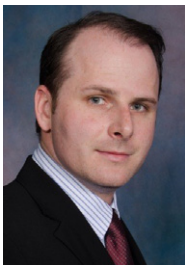
In light of the Court's opinion and Justice Ginsberg's inclusion of government motivational concerns, *Timbs* should prompt lawyers and judges in Florida to consider how the Eighth Amendment's Excessive Fines Clause applies if a state governmental actor seeks to impose excessive penalties or fines. While Article I, Section 17 of the Constitution of the State of Florida forbids excessive fines and other sanctions, including but not limited to cruel and unusual punishment, the wording of this state constitutional provision gives *Timbs* added significance. Consider first that Article I, Section 17 expressly obligates Florida governmental actors to construe Florida's "cruel and unusual punishment" prohibition "in conformity with decisions of the United States Supreme Court which interpret the prohibition against cruel and unusual punishment provided in the Eighth Amendment to the United States Constitution." In sharp contrast, Article I, Section 17 *does not* obligate a Florida governmental actor to follow USSC precedent when construing Florida's excessive fines prohibition. Accordingly, Florida lawyers and judges should analyze how the Eighth Amendment's Excessive Fines Clause applies post-*Timbs* whenever a Florida governmental actor proposes to impose penalties or fines – that arguably "are at least partially punitive" and excessive – to discern if the Eighth Amendment affords broader protection against excessive penalties or fines than does the Florida Constitution.

While Florida professional licensing boards are given statutory powers to impose administrative penalties against individuals who serve in the health care profession, AHCA has statutory authority to impose administrative and sometimes contractual penalties against an array of entities: health care clinics, home health agencies, Medicaid providers and other health care entities. While *Timbs* involved an individual, it is likely that *Timbs*' progeny will not limit the decision's applicability to individuals. Recent USSC decisions offer increasing support for the view that corporations and other business entities merit the very same protection under the Bill of Rights as must be afforded individuals. The Florida administrative lawyer whose client seeks to impose or oppose proposed fines under a state statute or agency rule should be prepared to assess how the Eighth Amendment Excessive Fines Clause applies to the exhaustion of administrative remedies doctrine and how to best preserve arguments for judicial review regarding this federal constitutional claim.

Tim Schoenwalder *practices in insurance, health care, licensure and contract procurement law as a shareholder at Meenan P.A. He graduated from the Florida State University College of Law, where he served as a member of both the Law Review and the Environmental and Land Use Journal.*

Protecting Mental Health Records and Psychotherapy Notes

By David Kurlander



In order to identify the importance of protecting psychotherapy notes, it is necessary to understand the differences between two different types of mental healthcare provider notes. Healthcare professionals take detailed notes as an essential component of patient care to diagnose and treat patients. Any identifying medical information relevant to the patient falls under the umbrella of protected health information under HIPAA (for covered entities), and is also protected under Section 456.057, *Florida Statutes*, and must remain confidential.

Mental healthcare providers typically create two types of notes: clinical notes (also known as progress notes), and psychotherapy notes. Progress notes are like bedside management notes. For example, progress notes may document that an individual takes Alprazolam (anti-anxiety medication) for anxiety, which was first prescribed on a specific date. In contrast, psychotherapy notes may record a patient's deep inner-most thoughts (sexual thoughts, fantasies, personal upbringing, etc.). Progress notes are meant to be shared with other healthcare workers to assist with the treatment and inform the medical staff of patient care, medical history, up-to-date progress, and other vital medical information.[1] Moreover, progress notes address four components, commonly abbreviated as "SOAP,": Subjective- patient's current condition as explained by patient; Objective- findings from a physical examination; Assessment- summary of a patient's diagnosis; and Plan- treatment, follow-ups, referrals, lab orders, and review of medication. These progress notes document the chief complaint, history of present illness, review of systems, present medications, past history, mental and physical status, assessment and diagnosis, and treatment plan.[2]

Unlike progress notes, psychotherapy notes do not typically include medication records, test results, treatment plans, and summary of progress. Psychotherapy notes are notes taken by a mental health professional (psychologists, psychiatrists, physicians, social workers, nurses, counselors, forensic and legal specialists, occupational and rehabilitation therapists, and other healthcare providers), which usually include the mental healthcare providers hypothesis, diagnosis, observations, and any thoughts or feelings they have about the patient.[3] Psychotherapy notes require special protection because these notes are the therapist's personal notes, which are meant to assist these professionals in performing their job. According to the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), "approaches to validating diagnostic criteria for discrete categorical mental disorders have included the following types of evidence: antecedent validators (similar genetic markers, family traits, temperament, and environmental exposure), concurrent validators (similar neural substrates, biomarkers, emotional and cognitive processing, and symptom similarity), and predictive validators (similar clinical course and treatment response)."[4] The information obtained from patients during a psychotherapy session is sensitive and of value to all professionals associated with various aspects of mental healthcare.[5]

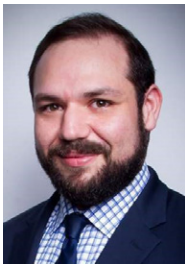
Patients do not have the right to access the mental healthcare provider's psychotherapy notes.[6] A mental healthcare provider may document within the psychotherapy notes that the patient is psychotic and dangerous, or the mental healthcare provider may not want the patient to reread the notes because the information could impair the patient's progress as the notes may cause the patient to re-live traumatic events.[7] Upon the mental healthcare provider's discretion, the mental healthcare provider could create a document of the summary to the psychotherapy notes.[8] If the patient demands the mental healthcare provider deliver the psychotherapy notes, then the mental healthcare provider should insist the patient contact an attorney. Florida Evidence Code, Section 90.503, states that "communication between psychotherapist and the patient is 'confidential' if it is not intended to be disclosed to third persons." In most instances, when a mental healthcare provider is issued a subpoena for psychotherapy notes, the court will approve a protective order that governs the confidential treatment of such documents. Additionally, a mental healthcare provider should timely respond to a subpoena in writing to inform the court that the mental healthcare provider is unable to comply with the subpoena or to assert privilege, and the court may hold a hearing to decide what information or records are protected.[9]

Healthcare providers cannot share psychotherapy notes without a patient's authorization. Psychotherapy notes are unrelated and separate from billing records. The HIPAA Privacy Rule does not require the healthcare provider or health plan to share a patient's medical information with other providers, except as authorized by the patient. If a mental health professional seeks to share the psychotherapy notes, the mental health professional must first obtain written authorization from the patient.[10] Mental healthcare professionals must keep their

See "Mental Health Records" on page 12

New Legislation Reforms Background Screening for Behavioral Health Care Treatment Providers

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



Florida's behavioral health care treatment providers are applauding the recent enactment of House Bill 369 (HB 369),[1] which they say will help to address a critical workforce shortage.[2] Effective as of July 1, 2019, HB 369 amends level 2 background screening procedures for individuals who, due to past, non-violent criminal conduct, may be ineligible from employment in a behavioral health treatment facility.[3] The Bill eases the burden for those seeking an exemption from disqualification for certain non-violent offenses and also provides AHCA and DCF with greater discretion to grant them.

Prior to HB 369, behavioral health employers were required to disqualify or remove an otherwise qualified employee if that person had been arrested for, found guilty of (regardless of adjudication), or entered a plea of *nolo contendere* or guilty to any of the 52 offenses prohibited by section 435, *Florida Statutes*.[4] Many of these individuals were disqualified due to past criminal conduct, which often occurred in connection with their previously unmanaged substance use disorder (SUD) or mental health issue.[5]

Yet Florida's Legislature recognized that these individuals are often uniquely qualified to provide treatment and recovery services based on their shared experiences—including criminal history—and diagnoses.[6] The Legislature's recognition of these unique qualifications was also recently acknowledged by DCF:

> In reading the lengthy and broad Legislative intent found in section 397.501(1) through (11), it is reasonable to conclude that the Legislature intended to allow for experienced and qualified individuals, like Petitioner, to help carry out the alcohol and substance abuse recovery scheme recognized so vital to Florida's public health.[7]

Reinforcing that intent, the Legislature amended background screening procedures in three significant ways. First, the bill expands the crimes for which individuals may receive an exemption from disqualification. Those who would have been disqualified for prostitution, certain burglaries, grand theft (third degree), certain forgeries, and substance-related attempt, solicitation, or conspiracy crimes now may seek an exemption without having to wait the three years after completing the terms of their conviction.[8] DCF must also now grant or deny all exemption requests within 60 days after receipt of a completed application. Finally, and perhaps most significantly, HB 369 provides AHCA or DCF the authority to grant "limited exceptions." That is, the appropriate agency may grant exemptions for those seeking to work solely in mental health and SUD treatment facilities, recovery residences, or in facilities that treat co-occurring substance use and mental health disorders.[9]

Prior to HB 369, Florida's background screening laws failed to take into account the special nature of the behavioral health care workforce. Those most qualified (and willing) to help others suffering from behavioral health conditions were often barred from employment due to their past, non-violent criminal conduct. This "one size fits all" approach led to a shortage of capable employees. As a result of HB 369, however, the background screening process under Chapters 394 and 397 should be more accessible for employers and employees, as it is now more aligned with the Legislature's commitment to help provide greater access to behavioral health care services for all Floridians.

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 regulatory compliance and transactions, with a specific emphasis on alcohol and substance use disorder (SUD) treatment facilities, mental health care programs, and recovery residence providers.*

See "Background Screening" on page 12

Health and Human Services Proposed Changes to ACA §1557: What will this mean for Floridians?

Barbara L. Kornblau, JD

In May of 2014, the Tampa-based AIDS Institute and the National Health Law Program filed a complaint with the U.S. Department of Health and Human Service's (HHS's) Office for Civil Rights alleging that four health insurance companies violated the antidiscrimination provisions found in Section 1557 of the Affordable Care Act (ACA). According to an article in the Miami Herald, they alleged these four health insurance companies placed all of their HIV drugs in the highest price tier and required preauthorization for treatment, thereby discriminating against people with HIV.

Florida's Office of Insurance Regulation intervened and reportedly put the insurance companies on notice that they were discriminating against people with HIV/AIDS in violation of Florida law that specifically protects people with HIV. Recent proposed federal regulatory changes could affect such cases in the future.

Section 1557 of the ACA prohibits discrimination based on race, color, sex, age, and national origin. This ACA provision insures no one is denied health services or health coverage or is discriminated against in the provision in health services or health coverage because of their race, color, national origin, sex, age, or disability. Section 1557 applies to any health program or activity, any part of which receives funding from HHS. Section 1557 is the first civil rights law to prohibit sex discrimination in the provision of health care and its regulations include gender identity. Sex discrimination has been interpreted to include abortions services. The current regulations have been interpreted to protect the LGBTQ community as well.

Several cases challenged the regulations with reference to several of the Section 1557 provisions. For example, in *Franciscan Alliance, Inc., et al. v. Burwell, et al.,* 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016), the Court issued a nationwide preliminary injunction, against the Section 1557 regulations.

HHS recently announced a Notice of Proposed Rule Making (NPRM) in the Federal Register. This proposed rule would do several things that will affect Floridians. For example, under the proposed rule, if another scenario arose similar to the discrimination against HIV in coverage case mentioned above, but for a Section 1557 covered group facing discrimination not specifically protected by Florida law, there would no longer be protection under Section 1557. This is because the proposed rule distinguishes between the *provision of health insurance* and the *provision of health care*, exempting much of the plans and products sold by insurance companies from Section 1557 protections. Some changes in the proposed rule would:

I. Limit the scope of health programs protected by Section 1557 from any health program or activity any part of which receives federal funding, and all programs administered by HHS and *to only health programs and activities administered by agencies established by Title I of ACA*. This means Floridians could lose much of the antidiscrimination protection they gained from ACA.

II. Eliminate the requirements to post notices about nondiscrimination policies; provide information about the availability of and how to request auxiliary aids and services; designate at least one employee to carry out compliance with Section 1557; adopt a grievance procedure with due process; and use taglines in the top 15 languages in each state, notifying people that interpretation services are available for people with limited English Proficiency. Florida's large population of non-native English speakers and people with disabilities will no longer have the right to be informed in their native language of how to request language services and other auxiliary aids and services for their health care service and how to file complaints, should they be denied services.

III. Delete provisions recognizing that Section 1557 includes a private right of action and limiting available remedies. Floridians will no longer have the same remedies if they face discrimination in the provision of health insurance and health care services.

IV. Reduce protection for the LGBTQ community, incorporate a religious exemption to the sex discrimination provisions and include exemptions for abortion services and refusal laws. It also erases all reference to discrimination against LGBTQ patients from several HHS rules. Together these mean members of Florida's LGBTQ community could be subject to exclusion from health care services if the provider claimed a religious exemption and could face other forms of discrimination that the HHS rules specifically protect against under the current rules.

Comments on the proposed rule were due August 13, 2019.[1]

Barbara L. Kornblau, JD, OTR, *a graduate of the University of Miami School of Law, focuses on disability law and policy. She was a member of the Section 1557 Coalition that wrote this provision of the Affordable Care Act and successfully advocated for its inclusion in the final bill.*

Endnotes

1 More information regarding the proposed rule is available from these sources:

Katie Keith "HHS Proposes To Strip Gender Identity, Language Access Protections From ACA Anti-Discrimination Rule, " Health Affairs Blog, May 25, 2019.

Jennifer Orr Mitchell & Jared M. Bruce, "HHS Proposes New Rule to Revise Section 1557 and Repeal Notice Requirements," The National Law Review, June 4, 2019.

HHS Office for Civil Rights, "Fact Sheet: HHS Proposes to Revise ACA Section 1557 Rule," May 24, 2019.

National Health Law Program webinar June 12, 2019: "Trump's Proposed Rollback of the ACA's Nondiscrimination Protections by the National Health Law Program."

BACKGROUND SCREENING

from page 10

Endnotes

1 Ch. 2019-159, Laws of Fla. (2019).

2 *Florida's Behavioral Health Workforce Wins Big on the Last Full Day of Florida's Legislative Session*, Fla. Alcohol & Drug Abuse Ass'n (May 3, 2019), https://www.fadaa.org/news/449921/Floridas-Behavioral-Health-Workforce-Wins-Big-on-the-Last-Full-Day-of-Floridas-Legislative-Session.htm.

3 "Mental health personnel" seeking employment in mental health facilities licensed under Chap. 394, *Florida Statutes*, are required to meet all level 2 background screening requirements per Chap. 435 or be granted an exemption from disqualification by DCF or AHCA. §§ 394.4572(1) & (2), Fla. Stat. (2018). Likewise, all owners, directors, chief financial officers, and clinical supervisors of SUD treatment facilities or recovery residences licensed or certified under Chap. 397 are required to meet the level 2 background screening requirements or receive an exemption from disqualification. §§ 397.4073 & 397.487, Fla. Stat. (2018).

4 §§ 394.4572, 397.4073, & 397.487, Fla. Stat. The requirement to disqualify or remove employees applies to the offenses prohibited under *Florida Statutes* or similar law of another jurisdiction. *Id.*; HB 369 also added new disqualifying offenses to section 408.809, *Florida Statutes*, for those seeking employment in SUD treatment facilities or recovery residences, bringing the screening standards for those facilities in line with mental health employee screening standards under Chap. 394. *See* Ch. 2019-159, Laws of Fla. 3, 6 (2019) & 394.4572, Fla. Stat.

5 *See* Fla. H.R., Final Bill Analysis 10 (2019), *available at* https://www.flsenate.gov/Session/Bill/2019/369/Analyses/h0369z1.CFS.PDF (recognizing that individuals who have recovered from SUD or other mental health disorder often have a criminal history that disqualifies them from employment per Florida's background screening process).

6 *See id.* at 11 ("[T]hese individuals bring many 'lived experiences' . . . which give them the ability to assist others in recovery.").

7 *S.T. v. Dep't of Children & Families*, Case No. 18-5149, 19 at n.15 (2019) (DCF Final Order in reversing denial of an exemption from disqualification).

8 2019-159, Laws of Fla. 4 (2019) (amending section 397.4073(4)(b) and individuals to seek exemptions for crimes under §§ 796.07(2)(e), 810.02(4), 812.014(2)(c), 817.563, 831.01, 831.02, 893.13, or 893.147, Fla. Stat. and any related criminal attempt, solicitation, or conspiracy under § 777.04, Fla. Stat.); s*ee* § 435.07(1)(a) (agency may grant exemptions from disqualification to employees otherwise disqualified for felonies for which at least three years have elapsed).

9 2019-159, Laws of Fla. 2, 4 (2019) (amending sections 394.4572 and 397.4073, Fla. Stat.).

MENTAL HEALTH RECORDS

from page 9

notes secure and confidential at all times to avoid a HIPAA violation. Progress notes differ in that they may be disclosed when the HIPAA Privacy Rule and Florida law permit, the patient authorizes the disclosure, the patient is incapacitated in an emergency situation, or in certain other limited circumstances. Therefore, it is necessary that psychotherapy notes are strictly controlled because a patient's access to the sensitive information may regress the psychotherapy treatment and be highly detrimental to the patient.

Mr. Kurlander *has a J.D. from Florida Coastal School of Law, an LL.M. in Health Law and Policy from Northeastern University, and runs a legal practice in Boca Raton, Florida. Additionally, Mr. Kurlander has lectured on medical malpractice at Northeastern University and lectured on bioethics.*

Endnotes

1 Sandy, Difference Between Psychotherapy notes and Progress Notes, https://www.ican-notes.com/2018/06/08/the-differences-between-psychotherapy-notes-and-progress-notes/ (last accessed July 5, 2019).

2 Interview with Ronald Kurlander M.D., Psychiatrist, July 8, 2019.

3 Sandy, *supra* note 1.

4 Diagnostic and Statistical Manual of Mental Disorders, fifth edition, American Psychiatric Association, pg. 20.

5 Id. at, Preface pg. xli.

6 https://www.hhs.gov/hipaa/for-individuals/medical-records/index.html (last accessed July 5, 2019).

7 Ronald Kurlander M.D., Psychiatrist.

8 *Id.*

9 Ofer Zur, Subpoenas and how to Handle Them: Guidelines for Psychotherapists and Counselors, https://www.zurinstitute.com/subpoena/, (last accessed July 9, 2019).

10 Sandy, *supra* n. 1.