Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with January – April 2024 articles on significant developments in health law that may be of interest to you in your practice.

These summaries are presented to HLS members for general information only and do not constitute legal advice from The Florida Bar or its Health Law Section. HLS thanks these volunteers who have generously donated their time to prepare these summaries for our members.

- **Alexis M. Buese, Esq., Bradley Arant Boult Cummings LLP.**
- **Ashley Creech, Esq., Epstein Becker & Green, P.C.**
- **Delia A. Deschaine, Esq., Epstein Becker & Green, P.C.**
- **Enrique Miranda, Esq., Epstein Becker & Green, P.C.**
- **Eric Werner, Esq., Epstein Becker & Green, P.C.**
- **Julianna Dzwierzynski, Esq., Epstein Becker & Green, P.C.**
- **Kathleen Premo, Esq., Epstein Becker & Green, P.C.**
- **Kathy J. Tayon, Esq., Tayon Law P.A.**
- **Lars Noah, Esq., Chesterfield Smith Eminent Scholar and Professor of Law, University of Florida**
- **Lisa Gora, Esq., Epstein Becker & Green, P.C.**
- **Michael P. Gennett, Esq., Polsinelli Law Firm.**
- **William J. Spratt, Jr., Esq.**
- **Eric Setterlund, Esq., Bradley Arant Boult Cummings LLP.**

Best,

Elizabeth Scarola, Esq., Epstein Becker & Green, P.C., HLS Editor in Chief
Adriana Báez, MD/JD Candidate, University of Miami, HLS Law Student Member
John C. Hood, Esq., John C. Hood PLLC, HLS Team Editor

OIG GUIDANCE

OIG Opinion Provides Guidance on Redemptions with Purchase and Payments that Span a Time Period

The U.S. Department of Health and Human Services Office of the Inspector General (the "OIG") recently issued an advisory opinion that provides valuable information about structuring a redemption of a physician's ownership interest in a healthcare entity where the purchase and payments will span a period of time. Such a structure is potentially problematic under 42 U.S.C. § 1320a–7b(b) (the "Federal antikickback statute") and other Federal and State healthcare regulatory laws.

OIG Advisory Opinion No. 23-12 (Favorable),[1] posted on January 3, 2024 (the "Opinion"), considers a structure for redeeming retiring physicians' ownership interests in a limited liability partnership (the "Requestor") where the physicians' partnership units will be repurchased by the partnership over a 2-year period (the "Arrangement"). The Requestor operates one hospital and indirectly owns and operates a second hospital through a wholly owned subsidiary.
In the Opinion, the OIG only considers the Federal antikickback statute and decides to issue a favorable advisory opinion.

The Arrangement

Under the Arrangement, the Requestor will make a one-time offer to physician owners in the Requestor, who reach the age of 67, to redeem their direct partnership units (i.e., ownership interests) (the "Units") in Requestor in 3 equal increments over a 2-year period for the fair market value of the Units at the time of each purchase, and in exchange the physician agrees to retire from the practice of medicine within 6 months of receiving the first redemption payment. According to Requestor, a physician retiring from the practice of medicine needs a 6-month period for an orderly wind down of his or her medical practice consistent with state law. Physician owners in Requestor who decline the one-time offer for redemption of their Units per the Arrangement will continue as owners in Requestor until retirement or death, at which point Requestor may redeem their Units per the terms of the partnership agreement of Requestor. The partnership agreement of Requestor does not restrict the physician owners in the Requestor from referring their patients to any healthcare individual or facility.

In particular, the 6-month period which follows the first redemption purchase and payment and precedes the physician's retirement from the practice of medicine is a potentially problematic aspect of the Arrangement considering the Federal antikickback statute's prohibitions. This is because during such 6-month period the retiring physician owner could change his or her referral patterns to help ensure that the physician owner receives his or her purchase price under the redemption terms.

The Federal Antikickback Statute's Prohibitions

[1] https://oig.hhs.gov/documents/advisory-opinions/1144/AO-23-12.pdf

The Federal antikickback statute makes it a felony to knowingly and willfully solicit or receive any remuneration in return for referring an individual to a person (or offer or pay any remuneration to any person to induce such person to refer an individual to a person) for the furnishing, or arranging for the furnishing, of items or services reimbursable by a Federal care program.

Also, the Federal antikickback statute makes it a felony to knowingly and willfully solicit or receive any remuneration, in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering (or offer or pay any remuneration to any person to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering) any good, facility, service, or item reimbursable by a Federal care program. Under the Federal antikickback statute, "remuneration" includes any kickback, bribe, or rebate, and can be cash or in kind.

OIG Decision and Reasoning

The OIG believes that the risk of fraud and abuse that the Arrangement presents under the Federal antikickback statute is sufficiently low to issue a favorable advisory opinion. In the Opinion, the OIG determines that the Requestor makes the redemption offer in the Arrangement on an objective basis unrelated to the volume or value of other business generated by the physician owners in Requestor. That is, the Requestor makes the redemption offer in the Arrangement to all physician owners in Requestor attaining age 67.

Additionally, the OIG determines that remuneration paid to the physician owners that accept the redemption offer in the Arrangement is unlikely to result in unfair competition. The OIG reasons that it is unlikely the Arrangement will cause the retiring physician to alter his or her referral patterns during the 6-month period between the first payment under the redemption offer and retirement from the practice of medicine. The OIG also notes that the 6-month period is time-limited and the Requestor certifies it is necessary to allow the physician owners in the Requestor who accept the redemption offer to wind down their medical practices consistent with state law requirements.

Conclusion

Importantly, the Opinion is only applicable to the Requestor and no others may rely on it. Nonetheless, the Opinion provides valuable information when structuring a redemption of a physician's ownership interest in a healthcare entity where the purchase and payments will be over time.

Careful analysis needs to be given to any redemption of a physician's ownership interest in a healthcare entity where the purchase and payments will be over time, to help ensure the structure complies with the Federal antikickback statute and other Federal and State healthcare regulatory laws, like the Federal physician self-referral law at Section 1877 of the Social Security Act (at times commonly referred to as the "Stark law"), and Florida's antikickback, patient brokering and self-referral laws.

Written by Kathy J. Tayon, Esq., Board Certified in Health Law, Shareholder, Tayon Law P.A.

Can They Do That? – A Response to a Competitor's New Business Model

The landscape of health law is littered with "creative" business arrangements introduced as health care companies compete for market share. Some are carefully structured to comply with regulatory guidance; some not so much. Nuance, regulatory ambiguity, and the complexity of health law present challenges for lawyers advising health care providers on whether a particular proposal will run afoul of applicable fraud and abuse laws. What is a health care company to do when a competitor introduces a "creative" and potentially illegal business arrangement that gives it an unfair advantage in the marketplace?

The client may ask its health lawyer, "Can they do that?" And, depending on the facts presented by the client, the health lawyer might advise the client that such an arrangement could be construed as an impermissible inducement to referral sources to refer business to the client's competitor in violation of federal and state law. The conversation then may turn to a discussion of the client's options to deter the competitor's anti-competitive and harmful conduct.

Those options may include, among others, filing a lawsuit and/or complaint with applicable federal and state law enforcement and regulatory authorities for investigation. However, because violations of fraud and abuse laws implicate both parties to an impermissible arrangement, the health lawyer would prudently advise the client that both the competitor and the client's referral sources could be subject to investigation and, if the arrangement is determined to be in violation of applicable law, both parties could be subject to administrative sanctions, civil liability, and/or criminal liability. That approach may not bode well for the client's relationships with its referral sources.

Other approaches include filing a Petition for Declaratory Statement to a state regulatory agency with proper jurisdiction to determine whether the arrangement is in violation of applicable state law. The client may also file a Request for an Advisory Opinion to the U.S. Department of Health and Human Services Office of Inspector General ("OIG") to determine if the arrangement would violate the Federal anti-kickback statute.

This article highlights a health care provider's (the "Requestor") objective and interesting approach in requesting an advisory opinion from the OIG to challenge its competitor's business plan. Clearly, the Requestor did not wish to enter into the proposed arrangement it described in its request (the "Proposed Arrangement"). In OIG Advisory Opinion No. 23-05, issued August 15, 2023 (the "AO")[1], the OIG described in detail Requestor's account of a business arrangement allegedly being offered by competitors to Requestor's referral sources, recounted Requestor's proposed business response, and advised the Requestor whether the Proposed Arrangement would generate prohibited remuneration under the Federal anti-kickback statute. The details of the Proposed Arrangement are not set forth in this article, but I invite the reader to review the AO in its entirety.

The AO states, "Requestor certified that it would enter into the Proposed Arrangement for competitive reasons because existing surgeon clients of Requestor are continually approached by other [competing] companies that are encouraging the surgeons to enter into similar arrangements,

[1] OIG Advisory Opinion No. 23-05 (Unfavorable), *issued* August 15, 2023.

and Requestor seeks to retain business from its existing surgeon clients that otherwise would be lost to those competing . . . companies."[1] The Requestor made it clear that it does not wish to enter into the Proposed Arrangement but would do so only "as required in specific situations where its existing surgeon clients wish to . . . [enter into the Proposed Arrangement] . . . and may not continue to do business with Requestor otherwise."[i2]

In the AO, the OIG cited to various Special Fraud Alerts, a Special Advisory Bulletin[3] and case law[4] dating from 1989 to 2017 in issuing an unfavorable opinion stating: "[W]e conclude that the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute, if the requisite intent were present, which would constitute grounds for the imposition of sanctions under section 1128A(a)(7) and 1128(b)(7) of the Act."[5] The Requestor appears to have achieved its desired result.

Conclusion

While Final Orders issued by Florida state agencies in response to a Petition for Declaratory Statement and Advisory Opinions issued by the OIG are applicable only to the requesting party/petitioner and are limited to prospective conduct and the facts presented, they represent the position of the applicable governmental agency with respect to the conduct described and often have a chilling effect on similar conduct by non-parties. In this case, the Requestor clearly stated its competitive purpose in requesting an advisory opinion from the OIG and obtained a response that may have leveled the Requestor's playing field, at least until the next "creative" business arrangement presents itself.

Written by: William J. Spratt, Jr., Esq.

[1] *Id.* at 3.
[2] *Id.*
[3] OIG, Special Fraud Alert: Joint Venture Arrangements (August 1989) *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 1994). OIG, Special Advisory Bulletin: Contractual Joint Ventures (2003). See also, Special Fraud Alert: Physician-Owned Entities (March 26, 2013).
[4] E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092
[5] OIG Advisory Opinion No. 23-05, *Supra,* at 7.

New OIG Advisory Opinion on ASCs and Physician Bonuses

The HHS Office of Inspector General recently published an Advisory Opinion[1] on ambulatory surgical centers (ASCs) that reminds us that not just any compensation paid by an ASC to its physician owners is protected by the ASC safe harbor to the Federal Anti-Kickback Statute (AKS). It is a favorable opinion regarding an ASC-employer's proposal to pay bonuses to its employed physicians. The bonuses to be paid were 30% of the ASC's income from procedures performed by the physicians, which procedures would have been the result of patient referrals by these physicians.

The OIG concluded that the bonuses would be allowable because the physicians were employees of the ASC and thus fit into the safe harbor for "bona fide employees". While not mentioning the safe harbor for physician investments in ASCs, the OIG did note that, if the physicians had been independent contractors of the ASC as well as owners and tried to pay the bonuses in the form of ownership distributions, it would potentially violate the AKS. The ASC safe harbor only protects ownership distributions based on the physician's percentage of capital investment in the ASC. It does not protect bonuses or distributions tied directly or indirectly to referrals of patients. This distinction is important because practitioners may be led to believe that fitting into the ASC safe harbor makes any form of payment by the ASC to its owners legitimate.

Written by: Michael P. Gennett, Esq.

[1] https://oig.hhs.gov/documents/advisory-opinions/1132/AO-23-07.pdf

ADMINISTRATIVE LAW [DEA, FDA, HHS]

Federal Preemption and State Restrictions on Gender-Affirming Care

Over the summer, I fielded inquiries about the possibility that actions by the U.S. Food and Drug Administration (FDA) could federally preempt new state restrictions on gender-affirming care. In theory, such a legal strategy might sidestep the need to lodge increasingly unsuccessful challenges under the Fourteenth Amendment. *See* Mitch Smith, *Alabama Can Carry out Transgender Care Ban, Appeals Panel Says*, N.Y. TIMES, Aug. 22, 2023, at A14 (reporting that substantive due process and related objections to such laws, recently adopted in more than twenty states, have worked less well of late). As it turns out, however, the Supremacy Clause offers little assistance in attempting to get around these state laws.

This same question may soon confront courts in a related context. Assuming that the license issued by the FDA for medication abortion survives the judicial challenge currently winding its way back up to the U.S. Supreme Court, judges may have to decide whether federal permission to sell that drug preempts state efforts to bar its continued use. *See* Lars Noah, *Listening to Mifepristone*, 80 N.Y.U. ANN. SURV. AM. L. (forthcoming Oct. 2023). As I note in that soon-to-be-published essay, answering this question will require attention to "a subtle but potentially consequential distinction between interdicting supply of the drug and interdicting demand for it." *Id.* at n.31. Although the Supremacy Clause likely operates to trump the rare state laws that directly forbid the sale of mifepristone, it may not stand in the way of the far larger number of states that would largely forbid its continued prescribing and dispensing by health professionals.

The treatment of gender dysphoria includes the use of drugs approved by the FDA for other purposes. *See, e.g.*, Azeen Ghorayshi, *Doctors Back Youth Gender Treatments but Call for Review of Data*, N.Y. TIMES, Aug. 4, 2023, at A14. A state law barring only such "off-label" uses plainly would not amount to a prohibition on further sales of these drugs. For a parallel, consider physician-assisted suicide: A few states have authorized health professionals to dispense (but not administer) powerful sedatives in limited circumstances when terminally-ill patients seek aid in dying, but most states continue to prohibit this practice without any serious suggestion that the FDA's approval of the drugs (for non-lethal uses) preempts these less permissive state laws. In the absence of implied preemption of the entire "field" (typically only found in connection with labor relations law and the regulation of nuclear power generation), federal inaction generally does not oust state power. *Cf.* Sprietsma v. Mercury Marine, 537 U.S. 51, 64-70 (2002) (holding unanimously that the U.S. Coast Guard's decision against mandating the installation of propeller guards on motorboats did not preempt a wrongful death claim that alleged a design defect).

What, however, if the FDA decided to approve a drug specifically for use in the treatment of gender dysphoria? Some commentators have suggested that such a formal federal endorsement of gender-affirming care would work to preempt state restrictions under the "obstacle" (a.k.a. "frustration of purposes") prong of implied preemption. That view confronts a few problems. First, in the Drug Amendments of 1962, Congress seemed to provide otherwise. *See* Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 8-9. Second, the U.S. Supreme Court evidently has moved away from obstacle preemption in favor of an expanded version of the "impossibility" (of dual compliance) prong of implied preemption. *See*

id. at 28-35 (discussing *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013)). Third, Congress has repeatedly expressed a principle of noninterference in the practice of medicine, thereby leaving states with the primary authority to regulate health care professionals. *See* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 155, 165-68, 173, 192 (2004).

Could the manufacturer of a drug approved in the future by the FDA to treat gender dysphoria successfully object that more restrictive state laws made it impossible to comply with conflicting commands from different sovereigns? As suggested above, an outright prohibition on the *sale* of such a drug should fall victim to implied preemption. A state prohibition on *use*, however, becomes trickier because it would seem to require establishing that such a state law amounted to a *de facto* prohibition on sale. *See* Lars Noah, *State Regulatory Responses to the Prescription Opioid Crisis: Too Much to Bear?*, 124 DICK. L. REV. 633, 643-45 (2020); *see also id.* at 659-60 (suggesting that laws singling out certain classes of otherwise comparable drugs would help to demonstrate that these imposed an undue burden on any protected rights of patient access). Notably, design defect claims lodged against pharmaceutical manufacturers get preempted even though they barely operate as *de facto* bans. Outside of the common law arena, such a showing would require paying attention to the particulars of the federal license and the scope of the state's restriction. Thus, getting a supplemental approval for an added indication on a previously approved hormonal agent would work less well than a single indication for gender dysphoria on a brand-new drug product. Moreover, in common with some states' restrictions on opioids, *see id.* at 647-48, many of the new limitations on gender-affirming care (including in this state) focus on adolescent use. *See, e.g.*, Patricia Mazzei, *Florida Bars Young People from Care to Transition*, N.Y. TIMES, May 6, 2023, at A13. This means that, for purposes of making preemption arguments, getting a single indication for gender dysphoria across all potential patient populations would work less well than an approval of that same use solely in adolescents.

More fundamentally, questions about legitimate clinical endpoints are (no pun intended) "trans scientific." *See* Lars Noah, *Confronting the Inevitability of Diagnostic Uncertainty Across Multiple Legal Domains*, in DIAGNOSES WITHOUT NAMES 59, 61-62, 67-68 (Michael D. Lockshin et al. eds., 2022). Like it or not, neither federal regulatory officials nor professional organizations enjoy a monopoly over defining the permissible contours of modern medical practice. *See* Lars Noah, *Pigeonholing Illness: Medical Diagnosis as a Legal Construct*, 50 HASTINGS L.J. 241, 287-96, 306-07 (1999); *cf.* Judge Rotenberg Educ. Ctr., Inc. v. FDA, 3 F.4th 390 (D.C. Cir. 2021) (invalidating the agency's ban on electrical stimulation devices when used to treat aggressive or self-injurious behaviors because, by singling out a particular purpose, it inappropriately attempted to regulate the practice of medicine).

Although implied preemption might come into play if the FDA approved a drug only for a narrow use that a state restriction rendered completely unmarketable within its borders (again along the lines that we now see emerging in connection with the abortifacient mifepristone), federal licensing that covered a broader range of authorized uses for a prescription product would give state officials the easy out of arguing that technically the drug could still be sold for other approved indications or in other approved patient populations. Absent legislation from Congress—or a still rarer legislative rule promulgated by the FDA—expressly preempting these state restrictions, or a judicial willingness to resurrect the old obstacle prong of implied preemption, shifting the off-label

use of existing drugs into their approved labeling will do little to increase access to gender-affirming care in those states that have decided to stand in the way of this medical practice.

Written by: Lars Noah, Esq. Chesterfield Smith Eminent Scholar and Professor of Law, University of Florida; author, *Law and the Public's Health: Cases, Controversies, and Covid-19* (Carolina Academic Press 2023), and *Law, Medicine, and Medical Technology* (Foundation Press 5th ed. 2022).

HHS Recommends Re-Classification of Marijuana as a Schedule III Controlled Substance – A Bellwether for the Future of Cannabis-ness

On August 30, an official at the United States Department of Health and Human Services (HHS) released one of the most significant announcements made at the federal level concerning marijuana reclassification. In a letter dated August 29, 2023, Rachel Levine (HHS Assistant Secretary for Health), provided a formal recommendation to Anne Milgrim (Agency Administrator) at the United States Drug Enforcement Agency (DEA) to reclassify cannabis from a Schedule I drug to a Schedule III drug under the Federal Controlled Substances Act (CSA).

A DEA spokesperson confirmed the department had received the letter with HHS's recommendation. The DEA has the final authority to reschedule a drug and will now initiate its own review of marijuana, a process that does not have any definitive timeline but could be moved along if determined to be an agency priority. Marijuana is currently listed as a Schedule I controlled substance under the CSA. A Schedule I classification is reserved for substances with no accepted medical use and a high potential for abuse while a Schedule III classification is reserved for substances having a legitimate medical use and "a moderate to low potential for physical and psychological dependence." Despite this difference, the manufacture, sale, distribution, or dispensing of a Schedule I or Schedule III controlled substance is illegal on a federal level without a federal DEA registration as is possession without a valid prescription. Therefore, the re-classification of marijuana in Schedule III would not make marijuana legal for every use at the federal or state level.

The HHS recommendation is predicated, via the FDA, on a scientific and medical evaluation of marijuana, using a statutorily required eight-factor analysis. The eight-factor analysis includes: (1) marijuana's actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significance of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; (8) whether the substance is an immediate precursor of a substance already controlled under the Controlled Substances Act. The DEA's own independent review of marijuana will include this eight-factor analysis, but it may also consider "all other relevant data" – permitting the DEA to look outside the statutory limits placed on the FDA's review. In addition, only certain components of FDA's eight-factor analysis bind the DEA. This effectively allows the DEA to adopt a different outcome than the FDA.

However, HHS' recommendation for a lower classification of marijuana is a bellwether for the eventual re-classification of the drug in Schedule III. The agencies rarely disagree on final scheduling placement. In 2008, however, the agencies disagreed about the transfer of hydrocodone combination products from Schedule III to Schedule II. Nevertheless, HHS eventually changed its recommendation that those products remain in Schedule III, and the agencies moved forward with DEA's desired re-classification.

Reclassification would mark a critical shift in thinking and regulation of marijuana and other Schedule I substances, which include drugs with a high risk of abuse (i.e., heroin, LSD, and ecstasy). Historically, both HHS and DEA have concluded that a drug must be approved by FDA

to be deemed to have an accepted medical use. Therefore, FDA had previously concluded that marijuana as a substance could not be transferred from Schedule I, and only an FDA-approved drug product that includes components of marijuana (i.e., Marinol, Syndros, Cesamet) could be transferred into a lower schedule. This resulted in the split-scheduling paradigm for marijuana that exists today. Therefore, HHS' recommendation must be predicated on the notion that DEA may transfer a substance out of Schedule I even if it is not an FDA-approved drug. This matters not only for the potential re-scheduling of marijuana, but also other Schedule I substances that are currently under development as medical therapies in the U.S.

Re-scheduling marijuana would also be broadly impactful to the regulation of the cannabis industry as a whole as it can potentially open more avenues for research, potentially allow cannabis businesses to bank more freely, and would eliminate the draconian impact Section 280E of the Internal Revenue Code has had on cannabis companies. Section 280E disallows any "deduction or credit . . . for any amount paid or incurred . . . in carrying on any trade or business if such trade or business . . . consists of trafficking in" a Schedule I or II controlled substance which is prohibited by Federal or applicable state law. If marijuana is reclassified as a Schedule III controlled substance, marijuana business would be able to deduct typical business expenses like any other business. A schedule III reclassification could also alter the landscape of marijuana regulation in the U.S. by potentially leading to insurance coverage and reimbursement for the drug as a covered benefit, dispensing of marijuana through a state-licensed pharmacy, loosening the restrictions on interstate shipment of the drug, and the facilitation of more research into the drug's effects and safe use.

Link to original post: https://www.healthlawadvisor.com/hhs-recommends-re-classification-of-marijuana-as-a-schedule-iii-controlled-substance-a-bellwether-for-the-future-of-cannabis-ness

Submitted by Delia A. Deschaine, Esq., Lisa Gora, Esq., and Julianna Dzwierzynski, Esq., Epstein Becker & Green, P.C.

FEDERAL LEGISLATION

Congress May Have a Vision for Psychedelic Regulation in the US

The latest attempt to expand the psychedelic world is making its way through Congress. On September 21, 2023, Congressmen Robert Garcia (CA-42) and Earl Blumenauer (D-OR) introduced the "Validating Independence for State Initiatives on Organic Natural Substances Act of 2023". Aptly titled the VISIONS Act, this legislation would, if enacted, protect legal psilocybin use from federal law enforcement intervention in any state or locality where psilocybin is legally permitted. The language in the Act specifically states that it aims to prohibit any federal funds from being used to prevent any state or local government from implementing their laws to "authorize the use, distribution, sale, possession, research, or cultivation of psilocybin." This would, in turn, close the significant gap that exists between state licit psychedelic businesses and state authorized medical marijuana businesses with respect to the risk of federal drug law enforcement.

The VISIONS Act also is a significant attempt to expand access to psychedelic use and treatment in the United States. Critics pan the bill as too slim, as it only includes psilocybin, but it is a monumental stride in an attempt to allow state psilocybin businesses freedom from some of the Schedule I federal tape that currently binds them. In contrast to attempts to de-schedule a particular substance, a process which can be challenging, uncertain, and potentially contingent on FDA-approval, this bill would create some immediate relief for businesses that provide psilocybin to individuals needing treatment in compliance with state law. Currently, psilocybin's federal Schedule I classification prevents broad treatment and research of psilocybin, potentially inhibiting the understanding and utilization of the substance. However, some of the recent research on psilocybin usage is promising, indicating that the drug can be utilized with positive effect for individuals suffering from debilitating diseases, such as anxiety, depression, addiction (substance use disorder), and PTSD.[1] Some of the research also has shown that psilocybin has a low potential abuse rate.[2]

Currently, psilocybin treatment is legal in Colorado and Oregon. Massachusetts also recently introduced a bill to legalize psilocybin for therapeutic, spiritual, and medicinal purposes. Because the VISIONS Act would, if enacted, relate to any "unit of local government," the efforts in several municipalities (e.g., Portland, ME, Berkeley, CA) to decriminalize or deemphasize enforcement of personal possession of psilocybin would also fall within the scope of the Act. Congressman Garcia stated that the VISIONS Act "empowers" states and localities against the federal government in an attempt to allow states to move forward in the industry and decriminalize psilocybin in the same way cannabis has been regulated. Further, according to Congressman

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[1] See, e.g., Stephen Ross, et al., Rapid and Sustained Symptom Reduction Following Psilocybin Treatment for Anxiety and Depression in Patients with Life-threatening Cancer: A Randomized Controlled Trial, 30 J. Psychopharmacology 1165, 1166 (2016); Robin Carhart-Harris, et al., Neural Correlates of the Psychedelic State as Determined by fMRI Studies with Psilocybin, 109 Proceedings of the Nat'l Academy of Sciences 2138, 2142 (2012); see also Matthew Johnson, et al., Pilot Study of the 5-HT2AR Agonist Psilocybin in the Treatment of Tobacco Addiction, 28 J. Psychopharmacology 983 (2014); Michael Bogenschutz, et al., Psilocybin-Assisted Treatment for Alcohol Dependence: A Proof-of-Concept Study, 29 J. Psychopharmacology 289 (2015).

[2] E.g., Matthew Johnson, et al., The Abuse Potential of Medical Psilocybin According to the 8 Factors of the Controlled Substances Act, 142 NEUROPHARMACOLOGY 143, 161 – 62 (2018).

Garcia, the Act seeks to bridge the gap between mental health care access, drug policy, and social equity.

Despite the parallels that exist between the VISIONS Act and the existing appropriations rider (known as the Rohrabacher-Farr amendments) that protects state marijuana businesses, there are some key differences between the two pieces of legislation. First, the VISIONS Act would limit the spending of any federal funds to interfere with state programs, and would protect medical, adult-use only, and general state decriminalization psilocybin programs. In contrast, the Rohrabacher-Farr amendments only apply to spending by the U.S. Department of Justice, of which the U.S. Drug Enforcement Administration is a component and are limited to protecting only state medical marijuana programs. Second, the VISIONS Act would, if enacted, apply to all U.S. states, commonwealths, and the District of Columbia, whereas the Rohrabacher-Farr amendments only apply to certain states and territories (albeit a significant number of them: the only states not included are Idaho, Kansas, and Nebraska).

It remains to be seen whether support for the VISIONS Act will gain the necessary traction in the coming months. Regardless, the legislation is an important signal of the federal branch's interest in propelling changes to psychedelic drug regulation in the U.S., proving this will be an interesting area to watch in 2024 and beyond.

Link to original article or post: https://www.healthlawadvisor.com/congress-may-have-a-vision-for-psychedelic-regulation-in-the-us

Submitted by Delia A. Deschaine, Esq., and Eric Werner, Esq., Epstein Becker & Green, P.C.

STATE LEGISLATION

Is Florida Next? An Increase in State Notice Requirements Across the Nation for Health Care M&A May Be A Sign of What is To Come in Florida

In late 2019, House Bill 711[1] was introduced in the Florida House of Representatives, which would have required parties to provide notice to the Florida Attorney General of certain transactions. Although this bill was ultimately withdrawn from consideration, the trend of transaction oversight in other states in recent years may signal that similar legislation may be reintroduced in Florida.

An increasing number of states are requiring advance notice of health care transactions. These requirements may delay transactions or result in confidential information becoming accessible to the public. New York[2], Connecticut[3], Massachusetts[4], Nevada[5], Oregon[6], Rhode Island[7], and Washington[8] are states that already require notice of certain health care transactions. Starting in 2024, California[9], Illinois[10], and Minnesota[11] will become the latest states to implement health care transaction reporting requirements. This reflects a growing concern among regulators that healthcare M&A, especially Private Equity backed acquisitions, may require additional oversight or approval. We have highlighted the most recent state notification requirements as examples of what state transaction reporting requirements are arising across the nation.

California

California implemented a notice requirement with the espoused goal of evaluating transactions that may have a material impact on the cost, quality, and market consolidation of California health care programs. California will begin accepting notices of health care transactions beginning January 1, 2024, for transactions that will close on or after April 1, 2024. Transactions closing prior to April 1, 2024, are exempt. Under the notice requirements, health care entities are to submit the notice of the transaction at least 90 days prior to the closing of a material transaction to California's Office of Health Care Affordability ("OHCA"). The statutory definition of a "health care entity" is broad enough to encompass most health care businesses and is even more broadly defined under California's proposed emergency regulations which are to be finalized and become effective before the end of the year. Further, while a seller entity may be small enough to avoid the reporting, the purchaser will likely qualify.

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[1] 2020 Fla. H.B. No. 711 (N.S.), 122 Reg. Sess. (West)
[2] See also, N.Y. Pub. Health L. §§ 4550-4552.
[3] Conn. Gen. Stat. § 19a-486i.
[4] Mass. Gen. Laws Ch. 6D §13.
[5] Nev. Rev. Stat. § 598A.370.
[6] Oregon Revised Statute §§ 415.500 *et seq*.; Oregon Admin. Rules 409-070-0000 *et seq*.
[7] See the State of Rhode Island Hospital Conversions Act.
[8] Wash. Rev. Code Ann. § 19.390.030.
[9] Cal. Health & Safety Code §§ 127500 *et seq*.
[10] Illinois HB-2222.
[11] Minnesota HF 402.

California's proposed emergency regulations also provide that OHCA will conduct a 60-day preliminary review to determine whether the transaction must undergo a Cost and Market Impact Review (CMIR). If a CMIR is deemed to be necessary, the CMIR will be completed within 90 days of the final decision by OHCA to conduct a CMIR, however, OHCA may extend the CMIR review by 30 days if it needs additional time to complete the review. OHCA may also toll the time periods when waiting for documentation related to the transaction or if waiting on other state or federal regulatory agencies or courts to review the transaction which may impact OHCA's review of the transaction.

On November 28, 2023, California posted notification of the proposed emergency regulatory action and OHCA's plans to file the emergency rulemaking package with the Office of Administrative Law ("OAL") at least 5 working days after the date of the notice. Upon filing, OAL will have 10 calendar days within which to review and make a decision on the proposed emergency action. If approved, OAL will file the regulations with the Secretary of State and the emergency regulations will become effective. When finalized, the proposed emergency regulations will provide more detail regarding health care entities, what circumstances require notice, and more information regarding the CMIR process. Health care providers and private equity investors that contemplate a transaction closing on or after April 1, 2024, in California will want to closely follow the release of the finalized regulations and consult legal counsel on the implications of the notice of health care transactions which could significantly delay the transaction.

Illinois

Illinois will also require notice of transactions, effective January 1, 2024. Health care facilities and provider organizations that are parties to a covered transaction must provide notice of the transaction to the Attorney General no later than 30 days prior to the closing or effective date of the transaction.

The purpose of the reporting is to allow the Attorney General the necessary information and time to determine if it desires to conduct an investigation or enforce state or federal anti-competitive laws then or at a later date. The Attorney General is provided a 30-day period to review and request additional information which will trigger an additional 30-day delay on the transaction from the date of the submission of the additional information. As a result, a transaction is subject to a minimum 30 day hold on completing a transaction.

Minnesota

On May 26, 2023, the Governor of Minnesota signed into law specific reporting requirements for certain categories of health care transactions. This reporting requirements vary depending on the annual revenues of the health care entities and increase in scope and scale on January 1, 2024.

The first phase of the regulations became effective in May 2023. This phase requires notice and data reporting to the Attorney General and Minnesota Commissioner of Health of all transactions where: (1) the health care entity involved in the transaction has average revenue of at least $80 million per year; or (2) the transaction will result in an entity projected to have average revenue of

at least $80 million per year once the entity is operating at fully capacity. Notice must be provided at least 60 days before the proposed completion date of the transaction.

Effective January 1, 2024, the reporting requirements broaden to include health care entities with lower annual revenues but for this category, the health care entity must provide certain data requirements to the Commissioner at least 30 days before the proposed completion date of the transaction, or, within 10 business days of the date the parties first reasonably anticipate entering into the transaction if the expected completion is less than 30 days.

Key Considerations:

These reporting requirements require the disclosure of sensitive information to state agencies and can result in significant transaction delays. While many of these requirements are new or even still evolving, it is important for any purchaser or seller to take these requirements into account and to consult with counsel to strategically plan how to mitigate the impact. Investors and sellers should work with their attorneys to carefully monitor the changing landscape around reporting and take steps to modify deal timelines wherever possible to close prior to the dates that reporting requirements go live and strategically assess what information must be disclosed and identify mechanisms to protect the confidentiality of such reports.

Written by: Kathleen Premo, Esq., Enrique Miranda, Esq., and Ashley Creech, Esq., Epstein Becker & Green, P.C.

Florida Bill Proposes Safe Harbor Against Breach Suits to Businesses Maintaining Recognized Cybersecurity Programs

[*Editor's Note: As of the publication of this newsletter, the Florida Legislature had passed CS/CS/HB 473, but the bill has yet to be presented to Governor DeSantis for his signature. It is effective upon becoming a law.*]

A recently introduced bill in the Florida Legislature would provide businesses operating in Florida, including health care providers, with a legal defense to data breach lawsuits if they maintain robust cybersecurity measures that meet government- and industry-recognized standards. Specifically, Florida House Bill No. 473 (H.B. 473), known as the Cybersecurity Incident Liability Act, was introduced and reported favorably in the Commerce Committee on Jan. 23, 2024, to provide a much-needed safe harbor from liability for businesses that implement sensible, industry-recognized cybersecurity measures. This act aims to incentivize businesses to achieve a higher level of cybersecurity by maintaining a cybersecurity program that substantially complies with industry-recommended frameworks.

Businesses that achieve substantial compliance with recognized frameworks outlined in H.B. 473 would be entitled to a "legal safe harbor," which could be used as an affirmative defense against tort claims arising from data breaches linked to alleged failures to adopt reasonable cybersecurity measures.

Alexis Buese, a key member of Bradley's Class Action Litigation team based in Tampa, played a pivotal role in introducing the bill by providing crucial testimony on behalf of the health care industry in favor of H.B. 473 before the Commerce Committee. Bradley has consistently been at the forefront of advocating for innovative solutions that empower businesses to mitigate unnecessary class action exposure. With H.B. 473, the approach to liability becomes proactive, encouraging businesses to enhance their cybersecurity practices while offering incentives for upscaling their security measures.

Safe Harbor Details

H.B. 473's "safe harbor" does not grant blanket immunity to a business facing a data breach lawsuit. Rather, it specifically applies only to tort claims, such as negligence, and businesses seeking to utilize the safe harbor must plead it as an affirmative defense in a lawsuit and demonstrate that their cybersecurity program complies with the law's requirements. Importantly, the safe harbor does not extend to contract-based claims arising from disputes with vendors or customers involving contractual relationships.

It's important to note that H.B. 473 does not establish a minimum cybersecurity standard that businesses must achieve. Instead, it encourages businesses to adopt and maintain cybersecurity programs in substantial compliance with industry-recognized frameworks without imposing liability on those that do not. The frameworks recognized by H.B. 473 include the following:

- The National Institute of Standards and Technology (NIST) Framework for Improving Critical Infrastructure Cybersecurity

- NIST special publication 800-171
- NIST special publication 800-53 and 800-53a
- The Federal Risk and Authorization Management Program security assessment framework
- The Center for Internet Security (CIS) Critical Security Controls
- The International Organization for Standardization/International Electrotechnical Commission 27000- series (ISO/IEC 27000) family of standards

Additionally, H.B. 473 also considers cybersecurity programs substantially aligned with federal requirements, including the following:

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA) security requirements in 45 CFR part 160 and part 164, subparts A and C
- The Health Information Technology for Economic and Clinical Health Act requirements in 45 CFR parts 160 and 164
- Gramm-Leach-Bliley
- The Federal Information Security Modernization Act of 2014

Notably, H.B. 473 takes a flexible approach to cybersecurity, considering various business-specific factors in determining the necessary scale and scope of a cybersecurity program to determine substantial alignment with standards recognized in the bill. These factors include the size, complexity, and nature of the business and its activities, the sensitivity of the personal information it holds, the availability and cost of security improvement tools, and the resources available for cybersecurity efforts.

What Does This Mean for Companies in Florida?

While H.B. 473 is not yet law, it signifies a positive step forward in recognizing and rewarding businesses that proactively adopt and maintain robust cybersecurity programs. As we move into the future, companies of all types and sizes, across various industries in Florida, should take the opportunity to assess the confidentiality, proprietary nature, personal data, or other sensitive information they hold. It is crucial to review and evaluate the effectiveness of your privacy and security measures. This evaluation should encompass the organization's overall culture concerning privacy and security, ensuring that both the leadership and employees are adequately focused on these critical issues.

Furthermore, businesses should conduct thorough risk assessments to identify vulnerabilities and areas at risk, implement additional security measures to mitigate these risks, review and enhance existing policies and procedures, establish a tested incident response plan, and update employee training to address the latest cyber threats. This proactive approach to cybersecurity aligns with the objectives of H.B. 473 and can help businesses in Florida stay ahead in safeguarding their data and operations.

Written by: Alexis M. Buese, Esq. and Eric Setterlund, Esq. Republished with permission. The article, "Florida Bill Proposes Safe Harbor Against Breach Suits to Businesses

Maintaining Recognized Cybersecurity Programs" was originally published on *Online and On Point* by Bradley Arant Boult Cummings LLP. Copyright 2024.

Alexis Buese's practice involves all aspects of commercial litigation, with an emphasis on class action, contract disputes, and real estate and consumer class action litigation. She has broadly defended the consumer products and services industries against the expanding array of class actions that challenge their products, methodologies, and procedures. Her clients include numerous consumer goods manufacturers and retailers, including apparel, furniture, food, vitamin and dietary supplement companies, and e-commerce companies. Alexis regularly represents clients in telemarketing litigation brought under the Telephone Consumer Protection Act (TCPA), Florida Telephone Solicitation Act (FTSA), and other state telemarketing and consumer protection laws, and she frequently writes and speaks on telemarketing compliance.

Eric Setterlund serves as counsel in Bradley's Healthcare and Cybersecurity and Privacy practice groups. He has extensive experience with matters related to healthcare privacy, security protections and regulatory compliance. Prior to joining the firm, Eric served as chief privacy officer and privacy and data counsel for BlueCross BlueShield of Tennessee. He draws upon his real-world business and program management experience to provide his clients practical advice for complex regulatory and transactional matters.

MEDICARE

Medicare Changes to Make Drug Coverage More Manageable in 2025

Within the last few months, the Centers for Medicare and Medicaid Services (CMS) has issued guidance that will reduce the financial burdens of paying for prescription drug coverage for Medicare patients. The guidance outlines the requirements for Medicare Part D sponsors. Sponsors are the non-governmental entities, mostly insurance plans, that contract with CMS to offer prescription drug coverage to Medicare patients. The purpose of the Guidance is to make drug coverage more affordable and more manageable for seniors and disabled persons. Beginning in January 2025, Part D sponsors who charge a deductible will be required to allow patients to spread the payment of the deductible, which can cost up to $545, over 12 months rather than having to pay the full deductible up front. Having to pay this up-front deductible before the first dollar of insurance kicks in has been onerous for many seniors living on a fixed income, causing some to put off getting the medications they need. Other changes taking effect January 1, 2025, include requiring Part D sponsors to:

- Make available recommended vaccines at no cost to patients.
- Cap out-of-pocket costs for a month's supply of each covered insulin product at $35.
- Limit out-of-pocket drug costs to a maximum of $2,000.
- Expand eligibility for the "Extra Help" assistance programs for low-income patients. The program makes benefits, such as no deductibles, no premiums and fixed, lowered copayments for some drugs available to these patients. Currently, about 300,000 patients nationwide are enrolled in Extra Help. This change will make the program available to an expected 3 million additional Medicare patients.
- Pay a rebate to Medicare if they raise prices faster than the rate of inflation.

These changes are part of President Biden's prescription drug pricing law, the Inflation Reduction Act of 2022.

Written by: Michael P. Gennett., Esq.