Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with January - March 2023 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.

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COVID-19

May 11, 2023, End Date for COVID-19 Public Health Emergency (PHE)

One day prior to the third anniversary of the start of the COVID-19 public health emergency ("PHE"), the Biden Administration announced that the PHE will end May 11, 2023. With a few exceptions, all regulatory flexibilities afforded providers during the pandemic will terminate on that date. Having previously been promised 60 days' notice prior to termination, providers now have 100 days to develop and execute on their return-to-normal plans.

Let's start with the exceptions: thanks to the Consolidated Appropriations Act, 2023, expanded Medicare reimbursement for telehealth services will extend through December 31, 2024. This includes:

- ✓ Continuation of waiver of geographic and location requirements
- ✓ Continuation of reimbursement for telehealth services furnished by physical therapists, occupational therapists, speech language pathologists, and audiologists
- ✓ Continuation of reimbursement for audio-only services
- ✓ Continuation of reimbursement for telehealth services furnished by federally qualified health centers and rural health clinics
- ✓ Continuation of use of telehealth to recertify eligibility for hospice
- ✓ Delayed implementation of the in-person visit requirement for initiation of tele-behavioral health services

However, there remain several outstanding issues to be addressed by the regulatory agencies:

- ✓ Will the expanded list of telehealth services remain in effect through the end of 2024?
- ✓ Will CMS continue to pay for telehealth services at the higher non-facility rate?
- ✓ Will CMS continue to permit the use of telehealth for direct supervision?
- ✓ Will CMS continue to reimburse certain hospital outpatient department services furnished via telehealth?
- ✓ Will the Office of Civil Rights and the Office of Inspector General revoke their respective notices of enforcement discretion relating to telehealth?

Separate and apart from Medicare reimbursement, the federal Controlled Substances Act authorizes the use of telehealth during a PHE to complete the required in-person medical evaluation prior to prescribing any controlled substance. Unless Congress acts, this flexibility will terminate on May 11, meaning a practitioner will have to conduct a face-to-face encounter with the patient prior to writing a prescription for a controlled substance after May 11, 2023.

The Consolidated Appropriations Act also extends the Medicare Acute Hospital Care at Home Program through the end of next year. As of January 17, 2023, 260 hospitals in 37 states have been approved for the program. If your organization had been considering participation but assumed it was too late to get started, now may be the time to pursue this opportunity.

Other than telehealth and hospital-at-home, the end is growing near. In August 2022, CMS released a roadmap for the eventual end of PHE waivers and flexibilities. At the same time, CMS published a series of fact sheets for specific provider types identifying applicable waivers and flexibilities:

- Physicians and Other Clinicians
- Hospitals and Critical Access Hospitals, Ambulatory Surgery Centers, and Community Mental Health Centers
- Teaching Hospitals, Teaching Physicians, and Medical Residents
- Long-Term Care Facilities (Skilled Nursing Facilities and/or Nursing Facilities)
- Home Health Agencies
- Hospice
- Inpatient Rehabilitation Facilities
- Long-Term Care Hospitals and Extended Neoplastic Disease Care Hospitals
- Rural Health Clinics and Federally Qualified Health Centers
- Laboratories
- Medicare Shared Savings Program
- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
- Medicare Advantage and Part D Plans
- Ambulances
- End-Stage Renal Disease Facilities
- Participants in the Medicare Diabetes Prevention Program

The roadmap and relevant fact sheet are excellent reference tools as providers fine-tune their return-to-normal plans. However, there are some practical issues CMS will need to address – hopefully soon. For example, if a patient is admitted to a skilled nursing facility prior to May 11 without a qualifying three-day hospital stay (as this requirement has been waived for the duration of the PHE), will Medicare reimburse the SNF for that admission if it extends beyond May 11?

After three years, the extraordinary tends to become ordinary. The numerous waivers approved to ease administrative burden during the pandemic have, in many cases, become standard operating procedure. Consider this partial list of flexibilities from which hospitals have benefitted during the PHE:

- Authentication of verbal orders within 48 hours

- Reporting requirements relating to death of ICU patients with soft wrist restraints
- Information sharing on post-acute providers during hospital discharge planning
- Form and content of medical records, record retention requirements, and deadlines for completion of records
- Providing information to patients on advance directive policies
- Utilization review and QAPI requirements
- Maintenance of nursing plan of care for each patient
- Updates to therapeutic diet manual
- Medical staff credentialing and privileges process
- CRNA supervision requirements
- Responsibilities of physicians in CAHs (physically present to provide medical direction)

The clock is now ticking to reinstate processes that fully comply with regulatory requirements. Consider this 100-day notice the grace period the government will afford providers to re-train staff and unravel revised processes. After that, it's business as usual.

Submitted by: Angie Caldwell, PYA

LICENSURE AND LICENSING ISSUES

Florida Telehealth Licensing Outlook

Generally, telehealth providers must be licensed within the state where the patient resides or is receiving care.[i] In response to the COVID-19 pandemic, nearly every state issued temporary waivers to medical professionals licensed in other U.S. states, which allowed providers to offer telehealth services to patients across state lines without the need to obtain licensing from the particular state in which the patient resided or received care.[ii] To combat the pandemic and expand telehealth services within the state, the Florida Department of Health issued an emergency order on March 16, 2020, which permitted medical professionals unlicensed in Florida to provide healthcare services to Florida residents affected by the coronavirus.[iii] Florida's telehealth emergency waivers ended on June 26, 2021.[iv]

Now, other states also are gradually rolling back these telehealth emergency waivers afforded to out-of-state healthcare providers during the early stages of the pandemic in favor of more permanent changes to regulate interstate telehealth delivery. In particular, Florida has been a first mover in establishing a permanent registration telehealth policy. During the 2019 legislative session, Florida lawmakers passed section 456.47, Florida Statutes, which authorized out-of-state healthcare providers to furnish telehealth services to patients residing in Florida and established standards of practice for telehealth services. After Governor DeSantis signed the law on June 25, 2019, the law took effect on July 1, 2019. Under section 456.47, all out-of-state healthcare

providers must register with the Florida Department of Health to furnish telehealth services and may not provide in-person services to Florida patients.

More recently, Governor DeSantis signed a new law amending section 456.47 to remove prior restrictions on the prescription of controlled substances via telehealth on April 6, 2022. Under the new law, telehealth providers may prescribe Florida patients all controlled substances except for Schedule II substances. While this amendment does permit out-of-state healthcare providers to prescribe controlled substances to Florida patients via telehealth, providers should know federal law also governs the prescription of controlled substances. Under the Ryan Haight Online Pharmacy Consumer Protection Act, a controlled substance may not be prescribed by means of the internet without a valid prescription. Providers must conduct at least one in-person medical examination of a patient before prescribing a controlled substance to patients. The Ryan Haight Act law provides seven exceptions to the in-person requirement, but these exceptions are narrow and apply only to providers in an institutional setting.

Another approach to telehealth licensing that has gained traction involves the adoption of an interstate compact, such as the Interstate Medical Licensure Compact. The compact allowed medical professionals an expedited alternative to obtain additional state medical licensure to qualify to practice medicine among IMLC member states. To date, the IMLC comprises 33 states, the District of Colombia, and Guam. Other states such as Massachusetts, New York, and North Carolina, have passed legislation to be admitted to the IMLC. Under the current administration, Florida is unlikely to join the IMLC as admission to the compact would require the Florida Legislature to overhaul the state's health care policy and pass new stand-alone bills which would be a significant commitment.

Two key issues to keep an eye out for in 2023 include potential legislation surrounding telehealth payment parity and the increase of telehealth fraud.

Payment Parity

In April 2022, the Federation of State Medical Boards ("FSMB") released an updated telemedicine policy for the first time since 2014.[v] The FSMB acknowledged that rapid growth and utilization of telemedicine technologies have dramatically transformed conventional healthcare delivery.[vi] As such, the FMSB intends to advise state medical boards on proper procedures to regulate the use of telemedicine technologies in medical practice to benefit the public.[vii] The FMSB observed that limiting insurance coverage for healthcare services delivered via telehealth may increase inequities in the access to healthcare.[viii] The FMSB recommends that health insurance plans should provide the same coverage extended for the cost of healthcare services delivered in-person on the same basis as those delivered through telemedicine.[ix]

Florida lawmakers have grappled with the issue to establish payment parity standards for telehealth services for years and faced challenges from state medical boards and professional associations.[x] Section 456.47, Florida Statutes, distanced Florida away from mandating payment parity for telehealth services at the same rate as in-person care. This law favors health insurance companies because they can direct negotiations and set reimbursement rates with telehealth and telemedicine providers with increased leverage.[xi] When permitted to negotiate separate rates with

telehealth providers, reimbursement rates for telehealth services are often lower than those for similar services provided in-person.[xii] Indeed, healthcare insurance companies staunchly oppose payment parity to negotiate reimbursement for telehealth services on a separate basis.[xiii]

Florida Medical Association President Ronald Giffler, MD, expressed his displeasure with the law in a letter addressed to Florida Office of Insurance Regulation Commissioner David Altmaier on March 19, 2020, in which he urged the state to require insurance companies to reimburse providers for telehealth services at equal rates as those paid for in-person services.[xiv] Giffler noted that multiple major insurance companies doing business in Florida had "uneven responses" and lacked uniformity regarding reimbursement policies for telehealth services.[xv] Additionally, Giffler asked Florida officials to ensure that payments rates for in-network providers of telehealth services did not vary substantially than the rates of payment established by the insurer for services delivered in-person.[xvi]

In November 2021, Florida Senator Loranne Ausley sponsored SB 726 to amend section 627.42396, Florida Statutes. The bill would have prohibited Medicaid managed care plans from denying and excluding coverage for covered healthcare services provided through telehealth and imposed new reimbursement requirements for health insurers relating to telehealth services.[xvii] The bill died in the Health Policy Senate Committee on March 14, 2022.[xviii] As the law stands "any contract provision that distinguishes between payment rates or payment methodologies for services provided through telehealth and the same services provided without the use of telehealth must be initialed by the telehealth provider."[xix]

Additionally, Congress approved a year-end omnibus legislative package on December 23, 2022, which extends Medicare telehealth service coverage through 2024.[xx] Providers will be keen to see an increase in investment in telehealth infrastructure to ensure that patients receive the incentives of telehealth technologies over the long run.

Telehealth Fraud

Another issue posed by the expansion of telehealth services and policy that healthcare providers and insurance companies should know concerns telehealth fraud. The widespread adoption of telehealth services during the pandemic has contributed to positive health outcomes and made healthcare more accessible in many instances. However, hospital systems and healthcare providers need to be aware that the expansion of telehealth has raised concerns of fraud and abuse and patient safety. The Department of Health and Human Services Office of Inspector General (HHS-OIG) issued an alert on July 20, 2022, warning healthcare providers to exercise greater caution when entering business arrangements with companies that purport to provide telehealth, telemedicine, or telemarketing services.[xxi] Some of these companies have enveloped physicians and non-physician providers to perpetrate fraudulent schemes by offering kickbacks to providers to generate orders or prescriptions for medically unnecessary medical equipment, testing, prescriptions, or other related items, resulting in submissions of fraudulent claims to federal health care programs.[xxii]

The Department of Justice has paid special attention to the rise of fraud in the telehealth space over the pandemic. The Center for Medicare and Medicaid Services issued a waiver to permit

Medicare payments for patients who received telehealth services at the outset of the pandemic on March 6, 2020.[xxiii] Under these flexible telehealth rules, the Justice Department has documented an increase in kickbacks paid to physicians in exchange for beneficiary referrals of medically unnecessary tests and orders across the Middle and Southern Districts of Florida.[xxiv] Federal investigations of telehealth fraud and abuse will not slow down as Congress continues to invest in and expand telehealth capabilities

Conclusion

Telehealth technology has great potential to become a key staple of healthcare delivery once public health emergency declarations terminate permanently. State and federal government policy decisions will dictate how the distribution of telehealth services evolves and whether parity will exist between traditional in-person healthcare delivery. Healthcare insurance companies, providers, and other stakeholders will shape these negotiations and hopefully find common ground to promote additional investment and adoption of telehealth infrastructure.

Submitted by Pierre Craig, Esq., University of Miami School of Law

FALSE CLAIMS ACT

Mind Games: SCOTUS to rule on what "knowing" means under the False Claims Act.

What does it mean to "knowingly" or "recklessly" violate the law when that law consists of highly complex and ever-changing regulations, which may be open to interpretation? The U.S. Supreme Court recently agreed to review that question in two consolidated cases from the Seventh Circuit: *U.S. ex rel. Tracy Schutte, et al. v. SuperValu Inc., et al*. and *U.S. ex rel. Thomas Proctor v. Safeway, Inc (*collectively, "SuperValu"). The central question before the Supreme Court is whether a relator can allege a cognizable claim under the False Claims Act ("FCA") if a defendant can prove that it acted in accordance with an objectively reasonable interpretation of regulations. The concept of intent – known legally as "scienter" – has proven to be difficult in FCA cases involving allegations of "legal falsity." In such cases, a defendant is typically accused of falsely attesting to compliance with conditions of payment or other requirements under government programs. In these cases, the relator is not alleging the absence of a product or service for which the government has paid. Rather, the relator typically asserts one or more claims based on allegations that the defendant failed to comply with regulatory conditions precedent to payment.

In *SuperValu*, the pharmacists-turned-whistleblowers allege that the defendants submitted false claims by failing to account for discounts when reporting the companies' "usual and customary" prices for prescription medication. Pharmacies are required to submit these "U&C" figures to the federal government, which factors those discounts into the reimbursement calculation. By not reporting the discounts, the pharmacies allegedly received inflated reimbursement from the government. Below, the U.S. District Court for the Central District of Illinois confirmed that pharmacies are, in fact, required under applicable regulations to report the discounted price. However, the Court also found that the relators in these two cases had failed to establish that the defendants acted "knowingly" or acted with reckless disregard or deliberate indifference to that requirement. Therefore, the Court held, the defendants could not be liable under the FCA.

The district court, as well as the Seventh Circuit on appeal, applied the Supreme Court's reasoning in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007). There, the Supreme Court held that a defendant does not act "willfully" or "recklessly" where its position is (i) supported by an objectively reasonable yet erroneous interpretation of the law (in that case, the Fair Credit Reporting Act) and (ii) there was no agency guidance to "warn away" the defendant from such a position. *Safeco*, however, is not a False Claims Act case. And some jurists are cynical about the impact of applying an objective standard to government fraud cases. In his dissenting opinion, for instance, Judge David Hamilton argued that extending *Safeco* to the FCA could create "a safe harbor for deliberate or reckless fraudsters whose lawyers can concoct a post hoc legal rationale that can pass a laugh test."

Other courts have refrained from embracing the objective standard. In 2017, in *United States ex rel. Phalp v. Lincare Holdings, Inc.*, the U.S. Court of Appeals for the Eleventh Circuit held that scienter requires a defendant must actually know, or they should have known, that its conduct violated a regulation." 857 F.3d 1148 (11th Cir. 2017). The Sixth, Ninth and Tenth circuits have since followed *Lincare*.

Ultimately, the Supreme Court's decision here has the potential to impact the viability of "scienter" based defenses to False Claims Act claims significantly. A clear, objective standard would enable defendants to capitalize on reasonable interpretations of complex regulations as a defense at earlier stages of cases. Conversely, if the Supreme Court were to codify a subjective standard, the net effect likely would be to decrease the number of False Claims Act cases adjudicated prior to trial.

The Supreme Court is expected to hear arguments in the consolidated cases in late April with a decision likely to follow this summer.

The above article was written by Jordan Cohen, Esq., and Noam Fischman, Esq. Akerman LLP, and was originally published on Akerman LLP's Health Law Rx Blog on January 31, 2023.

MEDICAID AND MEDICARE

Fix your weak links in your Medicaid claims

Medicaid providers and suppliers have likely discovered this the hard way. A provider's or supplier's enrollment in the Medicaid program may be insufficient to assure that their provision of a covered and medically necessary good or service to a Medicaid patient will be deemed reimbursable. That is because the Medicaid program will also look at the enrollment status of the provider *who **R**eferred, **O**rdered, **P**rescribed or **A**ttended* ("ROPA") *the patient referred* to the Medicaid provider or supplier. If that ROPA provider is not a Medicaid provider or enrolled as a ROPA provider, the chain of Medicaid eligibility will be broken and that claim from the recipient of the referral will be denied.

Since October 1, 2021, the Medicaid program began rejecting claims submitted by a Medicaid provider but pursuant to a referral, order, prescription or certification from an attending

provider who is not enrolled as a Medicaid provider or a ROPA provider. Then-newly issued Federal Medicaid Regulations require the registration of ROPA providers. ROPA enrollment is, essentially, a partial enrollment. A ROPA provider can refer, order, prescribe or attend to patients and the provider, supplier or facility receiving these services can bill Medicaid, but the ROPA provider cannot itself bill for Medicaid services without fully enrolling as a Medicaid provider.

This requirement has led to headaches for many Medicaid providers. Hospitals whose community based staff physicians are called in to attend a Medicaid patient through the emergency room, for example, may have discovered the problem when tests ordered are not reimbursable. Or when that physician sends a Medicaid patient home with a prescription and the patient seeks to fill it at their neighborhood pharmacy, that patient and that pharmacy may discover the medication is not reimbursable.

So what can Medicaid providers and suppliers do to avoid this problem? First, get the word out. Make sure your referral sources are aware of this issue and their role in causing claim denials for Medicaid patients they've treated. If in Florida, you can refer them to these Florida Agency for Health Care Administration Quick Reference Guides to get them started on the process. Second, check the resources in your state to identify whether your referral sources are either fully enrolled in Medicaid or as a ROPA provider. For example, in Florida, there are three different methods for determining whether your ROPA practitioner is already fully enrolled as a Medicaid provider or a ROPA provider:

1. URPL (Unenrolled ROPA Provider List) – The URPL is a resource available for all Florida Medicaid billing providers. The URPL contains a listing of unenrolled ROPA providers who have been identified on fee-for-service claims. These unenrolled ROPA providers are identified by their NPI. The URPL is updated on a quarterly basis and is available under the Resources section of the ROPA Provider Enrollment page of the public Web Portal.

Please note, providers identified on the URPL have not been validated to qualify for ROPA provider enrollment. Although a ROPA provider's NPI may be listed on the URPL, the provider must meet the enrollment requirements described in the ROPA Provider Enrollment Overview Quick Reference Guide (QRG).

2. NPI to Medicaid ID Search Engine – Billing providers may verify whether a provider is known to Florida Medicaid by using the search option found on the NPI to Medicaid ID Search Engine. Users will find a link to the search engine under the Resources section of the ROPA Provider Enrollment page. Additionally, users can navigate to the search engine from the homepage, hover over the Provider Services tab, look under the Support column, and select "NPI to Medicaid ID Search Engine." If a provider is known to Florida Medicaid, entering their NPI in the search engine will identify the provider's Medicaid ID, enrollment type, and other useful information.

3. Claims Edits – Informational only edits related to compliance with the ROPA requirements began on August 15, 2019. Claims edits will be enforced effective October 1, 2021. The error codes and Explanation of Benefit codes, and Claim Adjustment Reason

Code/Remittance Advice Remark Code combinations may be found in the ROPA Claims Changes QRGs. Billing providers may log onto their account on the secure Web Portal to view the PDF of their remittance advices.

For more information, check your state's Medicaid agency website or follow up with a health care lawyer who has familiarity with your state Medicaid agency. In Florida, see the Florida Medicaid FAQs or reach out to us with follow up questions.

The above article was written by Martin R. Dix, Esq. and Marcy Hahn-Saperstein, Esq., Akerman LLP and was originally published on Akerman LLP's Health Law Rx Blog on February 15, 2023.

REGULATORY BOARDS AND AGENCIES

NLRB finds unlawful confidentiality & non-disparagement provisions in severance agreements

On February 21, 2023, the National Labor Relations Board ("NLRB" or "Board") continued its aggressive application of the National Labor Relations Act ("Act" or "NLRA") to workplaces without union representation and lessened the value of severance agreements for all employers by finding it unlawful for an employer to merely proffer a severance agreement that includes broad non-disparagement and confidentiality provisions to an employee. In *McLaren Macomb,* the Board held that a severance agreement that contains a confidentiality clause and a non-disparagement clause was unlawful because, in the Board's view, these provisions impermissibly infringe on employees' rights under the Act. Specifically, the Board found that these two provisions limit employees' ability to discuss their wages, hours, and working conditions (which could include disparaging remarks) with other employees, prevent employees from assisting other employees seeking assistance, and hinder employees themselves from seeking assistance from the NLRB, unions, and other outside organizations.

Importantly, this decision applies only to employees covered by the Act, which means that supervisory and managerial employees are generally excluded; however, it is likewise important to note that neither title nor compensation are determinative in assessing whether an individual is included in the Act's expansive definition of "covered employees." It is also notable that union representation is not a prerequisite for the Act to apply to employees and their workplaces. Thus, the *McLaren Macomb* decision applies to employees at non-unionized workplaces who fall within the Act's statutory definition of an "employee."

This decision from the Biden Board overturned two Trump Board decisions, *Baylor University Medical Center* and *IGT d/b/a International Game Technology*, both of which allowed employers to include confidentiality and non-disparagement provisions in severance agreements.

The Language of the Provisions the Board Found Unlawful

The severance agreement at issue in this case contained generic confidentiality and non-disparagement clauses.

The confidentiality provision required the employee to recognize the terms of the Agreement as confidential and agree not to disclose such terms to "any third person, other than [a] spouse, or as necessary to professional advisors for the purposes of obtaining legal counsel or tax advice, or unless legally compelled to do so by a court or administrative agency of competent jurisdiction."

The non-disclosure provision broadly barred the employee from disclosing any information or knowledge the employee gained from their employment and prohibited the employee from making statements to other employees or the general public "which could disparage or harm the image of the Employer, its parent and affiliated entities and their officers, directors, employees, agents and representatives."

Neither disputed clause contained any carveout language that would permit exceptions, such as for communication with a government agency or cooperation with an administrative proceeding.

The Board's Holding

The Board held that these clauses were unlawful because they "broadly prohibited" employees from discussing wages, hours, working conditions, and labor disputes and that such "sweepingly broad" prohibitions have a "chilling tendency" on employees. The Board believes these provisions could prevent employees from criticizing an employer, complaining about or discussing their current or former workplace, cooperating with a government investigation, participating in agency proceedings, or supporting other employees – past, present, or future – in such activities. The Board noted that such "public statements by employees about the workplace are central to the exercise of employee rights under the Act." The Board, consistent with its ongoing attempts to unravel non-disparagement clauses, took particular issue with the lack of temporal limitations or subject limitations in the agreement.

The Board opined that without these limitations, the provisions would apply to any labor issue, dispute, or term and condition of employment with the Employer. Pointing to past precedent, the Board held that "…employee critique of employer policy pursuant to the clear right under the Act to publicize labor disputes is subject only to the requirement that employees' communications were not be so 'disloyal, reckless or maliciously untrue as to lose the Act's protection.'"[1]

The Mere Act of Proffering Such Provisions Found Unlawful

The Board has also taken the position that it is its duty is to protect the "broad grant of rights" afforded employees by Section 7 of the Act and concluded that the mere proffer of a severance agreement that conditions receipt of its benefits on the forfeiture of Section 7 rights violates the Act. In other words, whether or not the employee actually signs the agreement and accepts its terms is irrelevant. According to the Board, employers typically present separation agreements as "the quid pro quo" for severance benefits when employees are "particularly vulnerable." As such, according to the Board, merely proposing any such agreement that could

reasonably be construed to interfere with or restrain the exercise of employee rights under Section 7 of the NLRA is unlawful.

What Should Employers Do Now?

While the Biden-Board has made it a habit of undoing all Trump-Board precedent, the McLaren Macomb decision follows a growing trend by federal agencies to examine the terms commonly included in severance agreements. Separation agreements have long been subject to scrutiny by the Equal Employment Opportunity Commission. More recently, as we reported here, here, and here, the Securities and Exchange Commission has increased its focus on employers' agreements and procedures it contends interfere with employee access to the agency. Likewise, the Federal Trade Commission is currently seeking to prohibit certain restrictive covenants between employers and employees altogether, as we most recently discussed here. Several states have also enacted restrictions on the use of non-disclosure agreements in the wake of the #MeToo movement. Employers should review existing severance agreement templates in light of this recent NLRB ruling and other agency and legislative actions, and exercise caution before seeking to enforce an existing non-disclosure or non-disparagement provision against an individual who previously signed an agreement containing such a provision.

The above article was written by Susan Gross Sholinsky, Esq., Steven M. Swirsky, Esq., Neresa A. De Biasi, Esq., Ashley Krezmien, Esq., & Erin E. Schaefer, Esq. from Epstein Becker & Green, P.C. and was originally published on Epstein Becker & Green, P.C.'s blog on February 24, 2023.

May resident physicians use hospital DEA registration numbers off-site?

A Florida "resident physician" is someone who has completed their internship and graduated from medical school but is not yet licensed as a Florida medical doctor or osteopathic physician and who registers with the Department of Health as a resident physician. Resident physicians have to complete at least a one-year residency before they can take the licensing examination and become licensed physicians. As part of the process of training new physicians, Florida allows resident physicians to utilize the hospital's Drug Enforcement Administration (DEA) registration number to prescribe controlled substances listed in Chapter 893, FS, in the normal course of their employment. (Section 458.345, FS). The hospital assigns a suffix to the hospital's number for each resident. But where can these registrations be used?

In the early history of graduate medical education residency programs, residents were typically confined to practicing on hospital campuses. More recently, hospitals have expanded resident physician education to recognize the breadth of physician practice. Especially with the recent increase in hospital acquisition of physician practices, some graduate medical education programs include rotations through physician office practices.

Florida's law on resident physician prescribing does not strictly limit the use of the hospital DEA registration number on the hospital campus. It states that such controlled substance prescribing must be "through the use of a [DEA] number issued to the hospital or teaching hospital by which the person is employed or *at which the person's services are used*." So, if a Florida

resident physician were employed by the hospital at an off-site location such as a hospital-owned physician practice, arguably, Florida would not balk at such physician engaging in controlled substance prescribing using the hospital's DEA number at such physician practice.

However, meeting Florida requirements is only half of the analysis. The DEA also has a say in this matter as the primary agency that regulates controlled substance prescribing and its regulations address resident physician prescribing of controlled substances. The DEA regulations (21 CFR 1301.22), in relevant part, waive the requirement of a DEA registration under the following conditions:

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

1. Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;
2. Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;
3. The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;
4. Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;
5. The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12);

With regard to off-site resident physicians, the language of subsection (4), "[s]uch individual practitioner is acting only within the scope of his/her employment *in the hospital or institution*" raises troubling questions. While a resident physician may be acting within the scope of their employment at an off-site location, they are not necessarily "in the hospital or institution." There may be arguments militating in favor of satisfying that condition when the physician office is located on the hospital or institution's campus.

Furthermore, historically, DEA has frowned on the use of DEA registrations other than at the address associated with the registration, so off-site use may be problematic – though the DEA regulations prohibiting off-site use do not mention "prescribing" and are limited to locations where controlled substances are "manufactured, distributed, imported, exported, or dispensed." In light of these somewhat conflicting laws, we recently spoke to the staff at one of the DEA district offices. That staff member verbally confirmed the interpretation that off-site prescribing by resident physicians was not allowed.

So, here's the dilemma: Florida law appears to permit resident physicians to use the hospital DEA registration if employed by the hospital regardless of where the resident is performing services as a resident. The DEA, however, does not. It appears to limit the resident physicians' use of the hospital DEA registration to the site of the hospital, itself.

Is there a way to satisfy both regulatory schemes? The DEA rules also allow "hospitals/clinics" to obtain an "institutional registration." Could the off-site hospital-owned physician practice obtain its own institutional "clinic" DEA registration number to be used for resident physicians? That may satisfy the DEA's requirements, but it could raise a new issue under Florida law. Florida recognizes hospitals, but does not appear to recognize the DEA category of "clinics" for institutional registrations. Rather, Florida law contemplates only the issuance of hospital or teaching hospital DEA numbers for resident physicians' use and the statute doesn't authorize resident physicians' use of clinic DEA registrations. Would Florida consider an expansive reading of its statute to allow resident physicians to use a hospital-owned physician practice's institutional clinic DEA registration? And, if it did, would this meet the requirement of being authorized by the state jurisdiction? It is difficult to predict such a change in policy, but it would likely serve the public good to resolve this dilemma and would cause no harm, so it may be possible.

Change is unlikely to occur unless representatives of Florida's accredited Graduate Medical Education hospitals (and perhaps the medical schools as well) meet with Florida DEA to revisit this process on both sides such that Florida resident physicians receive the needed on-the-job education and training on controlled substance prescribing that all sides would want. It may require tweaking Florida's statutory scheme to allow resident physicians to use the clinic registration as well as possibly revising the DEA regulations or confirming their interpretation to get there. Or, perhaps creative minds can come up with another approach.

This problem is likely not limited to Florida. Other states with varying laws on off-site resident physician prescribing of controlled substances may encounter similar issues. Ideally, DEA, itself, should recognize this conundrum and provide national guidance on resident physician use of institutional DEA numbers at off-site resident physician training sites.

The above article was written by Martin Dix, Esq., Akerman LLP and was originally published on Akerman LLP's Health Law Rx Blog on February 16, 2023.

State attorneys general flex in a post-Dobbs world – can complying with federal regulatory guidance constitute racketeering activity?

Are State Attorneys General expanding their reach in this Post-Dobbs world? On February 1, 2023, twenty state Attorneys General signed letters to both CVS and Walgreens warning the giant retail pharmacies against mailing medications that could potentially be used to induce abortions. These letters are most notable for the legal posture they assume. The state Attorneys General penning this letter are purporting to emphasize enforcement of federal law (18 U.S.C. § 1461), *not* the state law of the respective states these Attorneys General represent. Press reports state that CVS and Walgreens plan only to distribute abortion-inducing medications where it is legal to do so. Nevertheless, these warning letters assert that each Attorney General has the right

to enforce federal law—typically the purview of *federal* prosecutors—against any retail pharmacy that mails abortion-producing medications within, to, or from jurisdictions that are less restrictive with respect to abortions. 18 U.S.C. § 1461 (mailing obscene or crime-inciting matter), the proverbial hammer cited in the two warning letters, criminalizes using the mail to send any medicine, among other things, for the purposes of "producing" an abortion.

Perhaps acknowledging the atypical nature of a state Attorney General attempting to invoke a federal criminal statute, the twenty state Attorneys General here cross-reference a federal anti-racketeering statute, known as the Racketeer Influenced and Corrupt Organizations Act ("RICO"). 18 U.S.C. §§ 1961 *et seq*. Section 1461 is among the statutes listed in the definition of "racketeering activity." 18 U.S.C. § 1961(1). Therefore, the warning letters highlight that a violation of § 1461 could give rise to civil liability under RICO. *See* 18 U.S.C. § 1964(c). In turn, the state Attorneys General contend that they, along with other private parties, have proper standing to assert a claim in federal court nationwide to enforce § 1461.

Like many risk-oriented issues raised in our post-*Dobbs* world, these warning letters pose novel legal questions. More than 650 cases have cited to § 1461 since the first published opinion in the 1870s. Yet, we are aware of no case that has sought to couple the concept of abortion and the federal racketeering statute. The dearth of guidance leads practitioners (healthcare and law practitioners, alike) to many significant questions and considerations:

1. Even if using the mail to facilitate abortions may be considered "racketeering activity" under the definition set forth in RICO, that definition does not itself create liability. RICO criminalizes, and by extension creates civil penalties, only against certain patterns of racketeering activity enumerated in the RICO statute. 18 U.S.C. § 1962 (a)-(d). The warning letters do not explain how the potential mailing of certain abortion-inducing medications could fit one or more of the statutorily defined patterns.
2. What legally cognizable harm might the state Attorneys General articulate to create standing to file suit under § 1964(c) if, as mentioned, a "mailing" does not touch upon a particular state attorney general's jurisdiction?
3. RICO provides civil relief only for damages to a "business or property." 18 U.S.C. § 1964(c). The twenty state Attorneys General do not explain how they might meet this RICO standard for a private civil suit against retail pharmacies. Nor do the letters explain how damages might be quantified.
4. For medications that are used for both abortive and non-abortive patient care (such as methotrexate, which can be used for inducing an abortion as well as treating rheumatoid arthritis), what, if any, duty does a retail pharmacy have to police the intent of the prescriber and/or the patient?

There is also a fundamental question about federal preemption. On January 3, 2023, the Food and Drug Administration ("FDA") modified its risk evaluation and mitigation strategy for mifepristone, an abortion drug that is utilized in tandem with misoprostol to terminate an early term pregnancy, in part to broaden the ability of retail pharmacies to dispense that drug (FDA Action). How would courts balance a regulatory environment in which the FDA has approved

dispensing certain prescriptions, on the one hand, and state Attorneys General efforts to seek civil liability against retail pharmacies that act consistent with such FDA Action?

Finally, as noted in the letters mentioned above, this dispute also raises the specter of potential future criminal prosecution by a new administration in 2024, which may have different prosecutorial priorities than the current administration. Even if retail pharmacies may be free to mail pertinent medications now, 18 U.S.C. § 1461 has a five-year statute of limitations. Based on this look back, current conduct may be subject to prosecution in the future if leaders with a different set of prosecutorial priorities assume the White House in 2024. Ultimately, in our post-*Dobbs* world, healthcare practitioners face a host of risks, the totality of which cannot be summarized in a blog post and may not be readily apparent at this time. It is critical for practitioners to partner with experienced healthcare and litigation counsel to manage the scope and breadth of that risk as best as possible.

The above article was written by Noam Fischman, Esq., and Lauren Gandle, Esq., Akerman LLP and was originally published on Akerman LLP's Health Law Rx Blog on February 13, 2023.

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[i] Federation of State Medical Boards, *The Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, (July 2022), https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf.

[ii] Federation of State Medical Boards, *U.S. States and Territories Modifying Licensure Requirements for Physicians in Response to COVID-19*, https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf (last updated December 21, 2022).

[iii] Emergency Order No. 20-002, https://www.flhealthsource.gov/pdf/emergencyorder-20-002.pdf?inf_contact_key=c1be7c474d297aa416752a23d2694901680f8914173f9191b1c0223e68310bb1

[iv] *U.S. States and Territories Waiving Licensure Requirements for Physicians in Response to COVID-19*, *supra*, note 2.

[v] *The Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, *supra* note 1.

[vi] *Id.*

[vii] *Id.*

[viii] *Id.*

[ix] *Id.*

[x] Eric Wicklund, *Florida Board of Medicine Votes to Abandon Telehealth Guidelines*, mHealthIntelligence, (August 9, 2019), https://mhealthintelligence.com/news/florida-board-of-medicine-votes-to-abandon-telehealth-guidelines.

[xi] *Telehealth*, Florida Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling, (March 6, 2022), https://floridasmentalhealthprofessions.gov/latest-news/telehealth/.

[xii] Angela K. Dills, *Telehealth Payment Parity Laws at the State Level*, Mercatus Center, (November 30, 2021), https://www.mercatus.org/research/policy-briefs/telehealth-payment-parity-laws-state-level.

[xiii] *Id.*

[xiv] Ronald Giffler, MD, *Commissioner Altmaier Letter*, Florida Medical Association, (March 19, 2020), https://www.flmedical.org/florida/Florida_Public/Docs/Coronavirus/Commissioner-Altmaier-Letter.pdf
[xv] *Id.*
[xvi] *Id.*
[xvii] The Florida Senate, https://www.flsenate.gov/Session/Bill/2022/726/BillText/Filed/PDF (last visited December 23, 2022).
[xviii] The Florida Senate, https://www.flsenate.gov/Session/Bill/2022/726 (last visited December 23, 2022).
[xix] FLA. STAT. ANN. § 627.42396.
[xx] Rachel Stauffer, *Omnibus Bill Extends Medicare Telehealth Flexibilities and HDHP Telehealth Safe Harbor*, McDermott + Consulting, (December 23, 2022), https://www.mcdermottplus.com/insights/omnibus-bill-extends-medicare-telehealth-flexibilities-and-hdhp-telehealth-safe-harbor/.
[xxi] United States Department of Health and Human Services — Office of Inspector General, *Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies*, (July 20, 2022), https://oig.hhs.gov/documents/root/1045/sfa-telefraud.pdf.
[xxii] *Id.*
[xxiii] Centers for Medicare and Medicaid Services, *Medicare Telemedicine Health Care Provider Fact Sheet*, (March 17, 2020), https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.

[xxiv] United States Department of Justice, *Telemedicine 2022 Enforcement Action: Case Summaries*, https://www.justice.gov/criminal-fraud/telemedicine-case-summaries (last updated July 21, 2022).