September 30, 2016

Dear Health Law Section Members:

The Section website has been updated with the August – September 2016 articles on significant developments in the health law arena that may be of interest to you in your practice. These summaries are presented to Section members for general information only and do not constitute legal advice from The Florida Bar, its Health Law Section, or Section members. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

Shantal L. Henriquez, Esq.

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Thank you.

Patricia Huie, Esq., HLS Team Editor
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FACILITY & PROFESSIONAL LICENSURE

Rule Changes for Community Pharmacies

The Board of Pharmacy recently revised the rules for community pharmacies. Fla. Admin. Code R. 64B16-28.1081. Under the revised rule, the prescription department of a community pharmacy must be open for a minimum of 20 hours per week, compared to the previous 40 hours per week minimum; but the Board of Pharmacy could approve shorter hours on a case-by-case basis. Any pharmacy that is not open for 40 hours per week is required to post the days and hours that the pharmacy is open, information for after-hours access, and have a written policy and procedure for transferring prescriptions in compliance with Section 465.026, Florida Statutes, or receiving an emergency dose pursuant to Section 465.0275, Florida Statutes.

The revised rule also allows a community pharmacy to delay commencing operations once the pharmacy permit has been granted but it must notify the Board office within 14days of receiving the permit of its election to delay operation commencement. The pharmacy also must notify the Board office within two business days of when it does commence operations. A community pharmacy that does not commence operations within six months of receiving the permit must provide a written statement to the Board office explaining why the pharmacy has not commenced operations, the efforts the pharmacy took to commence operations, and the date the pharmacy expects to commence operations.

Reported by: Michael L. Smith, Esq.

Hefty Penalty for Area of Critical Need (ACN) Licensee Practicing Outside ACN Facility

The Board of Medicine imposed a reprimand, a one-month suspension, and a $15,000 fine on a practitioner with an ACN license for multiple instances of practice outside of an ACN facility. DOH v. Alliance, M.D., DOH Case Nos. 2014-3707 and 2014-11390. Additionally, the practitioner must complete the Florida Medical Association course "Legal and Ethical Implications in Medicine: Physician's Survival Guide-Laws and Rules," five hours of continuing medical education in ethics, five hours of continuing education in risk management, and pay the Department of Health's investigative costs.

A physician practicing under an ACN license may only practice in a county health department; a correctional facility; a Department of Veterans' Affairs clinic; some community health centers funded by the United States Public Health Services Act; or an agency or institution that is approved by the State Surgeon General. The ACN licensee must also notify the Department within 30 days of accepting employment with a facility.

Reported by: Michael Smith, Esq.

LIFE SCIENCES

DEA Denies Petition to Reschedule Marijuana but Authorizes More Manufacturers to Expand Medical Research

On August 12, 2016, the Drug Enforcement Administration ("DEA") denied two separate petitions to remove marijuana from the Schedule I classification of the Controlled Substances Act ("CSA"). The first petition requested the DEA to reschedule marijuana as a Schedule II drug, whereas the second petition requested to reschedule marijuana under any schedule except under the Schedule I classification.

In reviewing the petitions, the DEA consulted with the Department of Health and Human Services ("HHS"), the Food and Drug Administration ("FDA"), and the National Institute on Drug Abuse ("NIDA") to conduct an evaluation on marijuana to determine its efficacy and safety as a medical drug. After the evaluation, the DEA determined that marijuana does not meet the standards for currently accepted medical treatment in the United States. This determination, coupled with marijuana's high potential for abuse, lead the DEA to deny the petitions at this time. The DEA's response to the petitions state that the DEA and FDA continue to believe that the best of course action regarding marijuana is to conduct clinical trials under the FDA's Investigational New Drug ("IND") application process rather than to reschedule marijuana, and to allow the FDA to determine whether marijuana is safe and effective for medical use.

In line with its decision that clinical research is the best course of action to determine whether marijuana can be nationally classified as a medical drug, the DEA issued a new rule adopting a policy to authorize more manufacturers to grow marijuana for scientific and medical research. For the past 50 years, the DEA has had only one manufacturer registered under the CSA to grow marijuana for federal research, the University of Mississippi. Now, the DEA seeks more applicants to supply the FDA with a more diverse selection of "cannabinoids" to allow the FDA to research the various types of cannabinoids that can be used to treat various ailments. Cannabinoids are the chemical compounds found in the marijuana plant that researchers isolate and use in medical treatment and research.

These decisions follow only a few weeks after the first licensed, medical marijuana dispensary opened in Florida on July 22, 2016, Trulieve, which offers medical marijuana for state-wide sale in the form of low-THC (tetrahydracannabinol) and medical cannabis. The DEA's decision to expand medical marijuana research can affect the variety of products to which licensed Florida medical marijuana patients will have access now that it is currently available to treat patients diagnosed with severe seizure disorders or a terminal illness. Florida authorized the cultivation, sale, and use of low-THC and medical cannabis to treat those patients under the Compassionate Medical Cannabis Act of 2014, as amended by the Right to Try Act.

Reported by: Shantal L. Henriquez, Esq.

PUBLIC HEALTH

Public Health Law and Policy and Perspectives

Preemption and Public Health – Lessons from the Federal GMO Disclosure Law
In July, Congress passed a bill requiring that foods containing genetically modified organisms (GMOs) display a federally-mandated disclosure. The bill, recently signed into law by President Obama, includes a provision expressly preempting all state and local GMO labeling regulations that are not identical to the new federal standard.

Resources

Medical Marijuana – State Regulatory Statutes Governing Use
https://www.networkforphl.org/resources_collection/2016/08/17/810/survey_medical_marijuana_state_regulatory_statutes_governing_use/?utm_source=Network+Report+8-18-16&utm_campaign=Network+Report+8-18-16&utm_medium=email&utm_content=248
This resource outlines conditions related to the use of medical marijuana, including patient qualifications, insurance coverage, use restrictions, and includes provisions for minors' use of medical marijuana.

Medical Marijuana – State Regulatory Statutes Governing Distribution and Consumption

https://www.networkforphl.org/resources_collection/2016/08/17/811/survey_medical_marijuana_state_regulatory_statutes_governing_distribution_and_consumption/?utm_source=Network+Report+8-18-16&utm_campaign=Network+Report+8-18-16&utm_medium=email&utm_content=248
This resource details state-specific regulations related to permitted forms of consumption, dispensing, cultivating, packaging, and taxation of medical marijuana, and summarizes cities', towns' and counties' powers to regulate the production of medical marijuana.

Career Opportunities

NHeLP Health Law Fellowships: http://www.healthlaw.org/about/job-opportunities
The National Health Law Program has two new temporary full-time positions for health law fellows, based in its Los Angeles, CA office and Carrboro, NC office. Both positions are immediately available and are funded through June 30, 2017. Ideal candidates will have strong research and writing skills, familiarity with the Medicaid program and public health law, the ability to work individually and in teams, and a demonstrated interest in using law to reduce disparities and improve health.

Judge won't block strict child vaccination law in California – CBS News

A U.S. District Court judge in San Diego ruled last week to uphold California's vaccination law. The law, which went into effect July 1, 2016, requires all children, except those with medical exemptions, to be vaccinated for certain infectious diseases before attending private or public schools or day care facilities. The law did not allow religious or personal belief exemptions.

FDA Calls for Zika Testing of All Blood Donations – Wall Street Journal

On August 26, 2016, the FDA recommended that all blood banks screen blood donations in the U.S. for the Zika virus. The agency advised that blood banks in these states begin testing in the next four weeks: Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina and Texas; and that blood banks in all other states test within 12 weeks.

Pregnant Women Advised to Avoid Travel to Active Zika Zone in Miami Beach– NY Times

In mid-August, local Zika virus transmissions were reported in Florida, prompting the CDC to issue travel advisories for two areas in the state: a one-square mile area in a neighborhood north of downtown Miami, and a 20-block stretch in Miami Beach. The CDC generally must defer to state officials when determining boundaries for areas of disease transmission and related travel warnings.

U.S. Affirms Its Prohibition on Medical Marijuana – Washington Post

On August 11, 2016, the DEA announced that marijuana will remain a Schedule 1 substance under the Controlled Substances Act, meaning it is illegal for any purpose, including medical use. Advocates for marijuana legalization hoped that the increase in states' legalization of medical marijuana would soften the federal government's stance on the drug. At least eight states will consider marijuana issues in this year's November election.

Grand Rounds: Preventing Suicide through a Comprehensive Public Health Approach
CDC Media Relations: (404) 639-3286

Suicide is a serious, but preventable, public health problem in the United States, with over 42,000 suicides among persons over the age of 10 in 2014. The overall suicide rate has increased by 27

percent since 2000. We, however, can work to reduce the number of people who consider suicide, the number who attempt suicide, and the number who die from suicide. Suicide is preventable by complementing mental health treatment with public health prevention strategies. A public health approach uses data to understand suicide; addresses the individual, family and community factors that contribute to suicide; reaches a broader segment of the population; and implements the best available prevention strategies. The risk for suicide can further be decreased by providing safe and appropriate communication to reduce the stigma associated with seeking help from others and using support systems, such as the National Suicide Prevention Lifeline (1-800-273-TALK).

Reported by: Rodney Johnson, Esq.

THIRD PARTY PAYORS

FLOIR Announces 2017 Premium Increase for Individual Major Medical Plans

On September 6, 2016, the Florida Office of Insurance Regulation ("FLOIR") released approved premium changes for the fifteen health insurance companies submitting rate filings for FLOIR's review. The rate filings were for plans to be sold both on and off the Exchange. On average, premiums will increase by 19% beginning January 1, 2017.

FLOIR noted that the approved percentages were approximately two percentage points higher than the increases requested by the insurers in their May 2016 rate filings. According to FLOIR, this increase is partly due to several insurers writing only off-Exchange policies in Florida for 2017. Insurers' decreased participation in the Exchange impacted risk pool estimates.

The rate information is subject to change until final approval from the Department of Health and Human Services.

Reported by: Monica M. McNulty, Esq.

Florida Telehealth Advisory Council Appointed

In April 2016, Governor Scott signed HB 7087, which is designed to pave the way for future telehealth reimbursement legislation. The new law created a Telehealth Advisory Council within the Agency for Health Care Administration ("AHCA"). On July 27, 2016, AHCA announced the names of the 13 individuals who have been appointed to the Council.

The Council is charged with examining the types of telehealth services that are available in the state and existing coverage for such services. By October 31, 2017, the Council must make recommendations to increase the use and accessibility of telehealth services, including identification of any barriers to access, in a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

The Council is chaired by AHCA Secretary Elizabeth Dudek, and is composed of the Florida Surgeon General Celeste Philip and the following appointees:

- **Elizabeth Miller, CRNP**. Chief Operation Officer of WellCare Health Plans.
- **Dr. Ernest Bertha.** Medical Director of Sunshine Health.
- **William Manzie.** Administrative Director of Telehealth Strategy for Memorial Healthcare.
- **Matthew Stanton.** Senior Director of Distance Health for the Cleveland Clinic.
- **Dr. Steven Selznick.** CEO/president for Selznick Consulting.
- **Darren Hay.** Senior Vice President of Ideal Life.
- **Monica Stynchula.** CEO of REUNIONCare and acting state president of AARP.

- **Leslee Gross**. Assistant Vice President of Operations for Baptist Health South Florida.
- **Dr. Kevin O'Neil.** Chief Medical Officer of Brooksdale Senior Living, Inc.
- **Dr. Kim Landry.** EMS Medical Director and Chief Medical Officer for Leon County EMS and Lifeguard Ambulance Service, Inc.
- **Dr. Sarvam Terkonda.** Site Medical Director for Connected Care in Florida for the Mayo Clinic.
- **Dr. Anne Burdick.** Professor of Dermatology, Leprosy Program Director and Associate Dean for Telehealth and Community Outreach for the University of Miami, Miller School of Medicine.
- **Mike Smith.** Telemedicine Program Development Director for Florida State University, College of Medicine.

Reported by: Monica M. McNulty, Esq.

TRANSACTIONS

Aetna Exits Majority of ACA Markets: Reaction to DOJ's Lawsuit to Thwart the Aetna-Humana Merger?

Aetna, Inc. recently announced that it would stop selling individual Affordable Care Act ("ACA") (also known as "Obamacare") plans in most major markets next year. Aetna plans to stop selling these plans in 11 of the 15 states where it was participating in the program, including Florida. However, Aetna will continue to sell plans on state exchanges in Iowa, Delaware, Nebraska and Virginia. Earlier this year, Aetna said it expected to lose over $300M on the plans. Both Humana Inc. and UnitedHealth Group Inc. have also stated that they plan to pull out of the ACA marketplaces.

Earlier this year, Florida regulators had conditionally approved Aetna's acquisition of Humana's Florida-based Affiliates (February 15, 2016). That conditional approval included a requirement that Aetna expand its offerings on the state exchange to include five additional counties by 2018 and extend its reach even further by 2020. Florida regulators had also conditionally approved Anthem's acquisition of Cigna's Florida-based affiliates (April 1, 2016).

However, the conditional approvals occurred before the U.S. Department of Justice (DOJ) sued to block both Aetna's plan to purchase Humana ($37 billion) and Anthem's plan to purchase Cigna ($54 billion) because "the transactions would increase concentration and harm competition across the country, reducing from five to three large, national health insurers in the nation." The DOJ and state attorneys general filed two merger challenges in the U.S. District Court for the District of Columbia alleging that the mergers "would harm seniors, working families and individuals, employers and doctors and other healthcare providers by limiting price competition, reducing benefits, decreasing incentives to provide innovative wellness programs and lowering the quality of care." Dept. of Justice Press Release, July 21, 2016.

In a July 5, 2016 letter from Aetna CEO, Mark Bertolini, to the DOJ, Aetna suggested that if the government blocked the merger then Aetna would begin withdrawing from the health insurance exchanges; and on August 15, 2016, Aetna announced that it would withdraw from most major markets.

Reported by: Anu Sagi-Nakkana, Esq.