August 2018

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with June through July 2018 articles on significant developments in the health law arena 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 the following volunteers who have generously donated their time to prepare these summaries for our members:

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ADMINISTRATIVE LAW UPDATES

Proof of Self-Defense is Insufficient to Defeat Unprofessional Conduct Claim in Board of Nursing Disciplinary Action

Section 464.018(1)(h), Florida Statutes (2018), states that a Florida-licensed nurse can be disciplined for engaging in "[u]nprofessional conduct, as defined by board rule." The Board of Nursing ("Board") has defined unprofessional conduct to include "[u]sing force against a patient, striking a patient, or throwing objects at a patient[.]"[1] However, an important question was recently raised in *Department of Health, Board of Nursing v. McGee* as to whether a nurse who uses force against a patient in an act of self-defense can be sanctioned by the Board.[2] The Administrative Law Judge ("ALJ") in *McGee* held that disciplining the nurse in that circumstance is appropriate.

In *McGee*, the Respondent was a certified nursing assistant ("CNA") who practiced in that profession for approximately 30 years. The Respondent worked at various healthcare settings throughout his career, including a New York prison psychiatric ward, hospitals, and drug and alcohol treatment centers. Aside from the incident at issue in *McGee*, the Respondent had never been subject to any disciplinary proceedings related to his CNA license.

In February 2017, while working at a drug and alcohol treatment center, the Respondent was confronted by an agitated patient that was "belligerent, spewing vulgar and racist epithets, and generally creating a scene."[3] The exchange was captured on a surveillance video. Right before the exchange with the Respondent, the patient is seen in the video springing from the bench he was sitting on in the recreation area, stripping off his jacket, and walking quickly towards the building. The patient's posture in the video is described by the ALJ in the Recommended Order as "agitated and aggressive, with chest-thumping followed by outstretched arms."[4] At the same time, the Respondent can be seen in the video footage approaching the patient calmly and in a non-threatening manner. The Respondent approached the patient "in an effort to de-escalate the situation, and to move away from the other nearby patients to minimize the possibility of their involvement."[5] This was consistent with the de-escalation training the Respondent had received throughout his career. As the Respondent approached the patient, the patient turned to the Respondent, with fists clenched, insulted the Respondent by using a racial slur, and then feigned a blow towards the Respondent. In response, the Respondent struck the patient several times in rapid succession in what the ALJ described as "a reflexive act of self-preservation."[6] This act was the basis for the administrative complaint filed against the Respondent.

In reviewing this matter, the ALJ made several findings that the Respondent was acting in self-defense due to the Respondent's "legitimate fear and anticipation of assault."[7] However, the plain meaning of the statute and the rule does not contain an exception for actions taken in self-defense. Accordingly, the ALJ held that the Respondent, although acting in self-defense, engaged in sanctionable, unprofessional conduct. The ALJ stated that, based on Florida precedent, "[p]enal statutes must be construed in terms of their literal meaning, and words used by the Legislature may not be expanded to broaden the application of such statutes."[8] As such, whether the Respondent's action was defensive and reactive bears, instead, on "the severity of the appropriate penalty within the range established in the penalty guidelines."[9]

The ALJ in this matter ultimately held that "[t]he circumstances of this case, as set forth herein, clearly call for a penalty less than the maximum" and, therefore, recommended that the Respondent complete one year of probation, pay a fine of $50, and pay the costs related to the investigation and prosecution of this matter.[10] Notably, however, a Final Order has not yet been issued by the Board of Nursing; as such, it is unknown whether the ALJ's findings and ultimate holding will be upheld in the Final Order.

Submitted by: Angelina Gonzalez, Esq., Panza, Maurer & Maynard, P.A.

COMPLIANCE UPDATES

Changes Expected to Come to the Stark Law as CMS Seeks Public Input

On June 25, 2018, the Centers for Medicare & Medicaid Services ("CMS") published a Request for Information ("RFI") about the physician self-referral laws, otherwise known as the Stark Law. [11] The Stark Law was originally enacted in 1989 and named after Pete Stark, the California Congressman who proposed the law. The Stark Law seeks to prevent physicians from obtaining wrongful compensation in exchange for patient referrals to either themselves or to entities in which the physicians or their immediate family members have a financial interest.[12] Since its inception, the Stark Law has changed dramatically into a complex framework of extensively defined legal terms with various exceptions.

This RFI comes at an integral time for CMS, which has been encouraging "value-based health care" over the previous "volume-based health care" system. A value-based system is intended to encourage provider relationships and collaboration to effectively coordinate quality care with better results, rather than to encourage a higher quantity of health care treatments. However, the Stark Law does not fit neatly into the new value-based system model.

Seema Verma, CMS Administrator, explained that the Stark Law needs to change to reduce the high regulatory burdens placed on providers. In fact, CMS identified Stark Law compliance as one of the top areas of regulatory burdens placed on providers.[13]

In the American Medical Association's ("AMA") March 2018 congressional statement, the AMA called the Stark Law and the federal Anti-Kickback Statutes "outdated" and stated that they "stand[] in the way of achieving the goals of the new payment systems." Recognizing the conflicts between the new health care model and these laws, the AMA asked Congress to create new exceptions that are "designed to foster collaboration in the delivery of health care and incentivize and reward efficiencies and improvement in care." The AMA also asked Congress to limit the Stark Law's application only to ownership arrangements instead of all arrangements implicating financial interests.[14]

The public is invited to provide additional insight into how the Stark Law should be changed to better accomplish its anti-fraud and abuse goals, while also supporting a value-based health care system. Specifically, CMS is requesting comments on how to create a new Stark Law exception that encourages value-based care and re-defines certain key terms such as "fair market value."

CMS is also asking the public for opinions on the practicality of the already existing Stark Law exceptions. This public comment period is open through August 24, 2018.

While the current Stark Law largely depends on prohibiting compensation based on high volumes of patient referrals and business generated through provider relationships, it is expected that CMS will create a new exception that focuses on fostering such provider relationships. Should this new exception be enacted, providers may have more opportunities to structure compensation arrangements beyond the current exceptions.

Submitted by: Jocelyn E. Ezratty, Esq., Di Pietro Partners, LLP

LEGISLATIVE UPDATES

Emergency Doctors Sue Anthem in Federal Court for Restrictive Emergency Room Policy

On July 17, 2018, American College of Emergency Physicians and the Medical Association of Georgia filed a lawsuit against Anthem Blue Cross and Blue Shield of Georgia ("Anthem") on behalf of emergency physicians to force the health insurer to rescind its current policies that allow it to deny coverage of emergency room care when certain diagnoses are resolutely indicated.[15]

The lawsuit, filed in the United States ("U.S.") District Court in Atlanta, suit alleges that Anthem's current policies cause both providers and patients to operate in fear of denial of payment of essential and needed emergency patient care in violation of the Emergency Medical Treatment and Active Labor Act of 1986 ("EMTALA"), [16] the Patient Protection and Affordable Care Act ("ACA"),[17] the Employee Retirement Income Security Act of 1974 ("ERISA"),[18] and the Civil Rights Act of 1964.[19]

Anthem, based in Indianapolis, is the second-largest health insurer in the U.S., operating in 14 states with approximately 40 million health insurance members and $3.8 billion in net income. The company first introduced its "avoidable ER program" policy in 2015 in Kentucky, and expanded the policy to insurance markets within Georgia, Missouri, Indiana, Ohio, and New Hampshire. The policy's goal is to reduce the patient trend and subsequent behavior of going to a hospital emergency department for what results in non-emergency care that may cost up to 10 times more than the amount of urgent care.

Under the policy, Anthem may retroactively deny payment for emergency care and treatment in more than 120 distinct situations where patients were determined post-treatment not to have suffered from an "emergency" condition. Conditions that may seem emergent to a patient but may warrant claims rejections under the policy include bronchitis, contusions, sprains, and low back pain, among others. In this case, the plaintiffs allege that patients and emergency room physicians, who are often independent contractors, risk receiving large emergency room bills because they will be denied payment for care rendered or received pursuant to Anthem's policy.

Under EMTALA, also known as the "anti-dumping law," hospitals are required to medically screen and stabilize any patient that presents at an emergency department regardless of the patient's ability to pay. Given the additional cost of such emergency care, insurers began requiring that

patients obtain pre-authorization prior to receiving payment for care to help reduce costs. This practice, in turn, prompted a revision under EMTALA, enacted under Balanced Budget Act of 1997, called the "prudent layperson" standard which extended to all Medicare and Medicaid plans. Similarly, 47 states enacted statutes enforcing the prudent layperson standard.

The standard revised what constitutes an emergency medical condition. Generally, the prudent layperson standard states that an emergency medical condition is any condition that would require a person of typical or average knowledge of health and medicine to believe the condition constitutes an emergency, i.e., could result in serious patient jeopardy, serious impairment to bodily function, or serious dysfunction to a bodily part. In 2010, the standard was extended to all health plans under the ACA. Subsequently, under this standard, payment for emergency care by an insurer is based on the prudent layperson standard.

After pressure from patients and physicians, in February 2018, Anthem outlined criteria that would allow for exceptions to the policy for when certain care would be provided, including when patients travel out of state or if specifically directed to go to the emergency room by a provider. However, the basic tenets of the policy remained in place.

A month later, in March 2018, Senators Clair McCaskill (D-MO) and Ben Cardin (D-MD) sent a letter to the U.S. Department of Health and Human Services and the U.S. Department of Labor to ask that the agencies investigate the payment denials by Anthem and the likely violations of federal law. The Senators' letter stated that Anthem forces patients to act as medical professionals while experiencing an "urgent medical event."

Healthcare providers, insurers, regulators and patients should closely monitor this case as the decision will significantly impact similar insurance company policies throughout the country that restrict payment for emergency room care and consequential treatment.

Submitted by: Marguerita Brunson Sims, Esq., Carlton Fields

Expansion of Medicare Advantage Supplemental Benefits
A New World of Opportunities for Providers

Hospitals, health systems, provider groups, and residential and community-based long-term care providers ("Providers") should revisit their relationships with Medicare Advantage plans ("MA Plans") in light of recent federal legislative and regulatory developments in the rules related to Medicare Advantage ("MA") supplemental benefits.[20] In particular, Providers should consider how they can partner with MA Plans operating in the Florida market to jointly offer new categories of supplemental benefits, including offering new types of support services for people with chronic conditions and services targeting populations with certain diagnoses.

Regulatory Changes:
The Centers for Medicare & Medicaid Services ("CMS") recently finalized MA regulatory changes ("Final Rule") that allow MA Plans to offer "targeted" supplemental benefits that are medically related to a specific disease condition, provided the Plan continues to comply with the non-discrimination requirements. MA Plans are now allowed to determine which diagnoses or

health conditions they choose to offer these targeted benefits and they may vary them at the county-level. Under the Final Rule, MA Plans also are expressly allowed to have different cost sharing for benefits covered by specific providers. It will be important for MA Plans to identify in their bids and in their Evidence of Coverage documents which supplemental benefits are offered as "standard" or "targeted" supplemental benefits.

Legislative Changes:
The Bipartisan Budget Act of 2018 further expands the changes from the Final Rule to allow for supplemental benefits targeting beneficiaries with specific chronic conditions. The biggest change from the Bipartisan Budget Act of 2018 is that these chronic-condition-targeted supplemental benefits do not need to be expressly health related, provided that the services "have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee." This is a new exception to the long-standing medical necessity rules for MA and allows MA Plans to design supplemental benefits that address social determinants of health and in some cases, appear more like traditional, long-term care services.

Implications for Providers:
The new flexibility in the scope and design of supplemental benefits offers providers new business opportunities to offer a full spectrum of newly reimbursable services. The new supplemental benefit rules will create new streams of funding for services targeting high-risk populations and for non-medical services that can help reduce unnecessary utilization. In addition, because supplemental benefits are not subject to network adequacy requirements, they can be covered through a single provider. This allows for a new focus on "single source" care where plan members may seek care from a provider for all their services, supplemental and otherwise.

MA Plans are interested in partnering with sophisticated providers for the supplemental benefit offerings. Providers should consider the populations they currently serve or can serve and explore which supplemental service offerings best align with their care model and competencies. Providers should then take a proposal to the MA Plans in their region. Although MA Plans will not be able to implement the new supplemental benefits created by the Bipartisan Budget Act of 2018 until plan year 2020, MA Plans will be submitting bids defining these services in less than a year. Considering the timeline for implementing projects like this, Providers should immediately begin assessing the potential for their market and work with experienced MA counsel to begin discussions with MA Plans as soon as possible.

Submitted by: Kathleen M. Premo, Esq. & Kevin J. Malone, Esq., Epstein Becker Green, PC

Health-Related Laws with an Effective Date of July 1, 2018

The following provides an overview of health legislation passed during the 2018 Legislative Session with an effective date of July 1, 2018. The bills are presented alphabetically by subject. The summary information is not intended to be an exhaustive legal review but is intended to provide you with sufficient background to know whether it merits further review by you or your clients. For those who represent facilities, please note the comprehensive Agency for Health Care Administration ("AHCA") Bill (SB 622) and for those representing physicians, the bill addressing controlled substance prescribing is a must read (HB 21). Additional information (bill language,

amendments, and staff analyses) can be found on the Florida Senate and Florida House of Representatives websites – **www.flsenate.gov** and **www.myfloridahouse.gov**, respectively.

Cardiac Programs

HB 283 was approved by the Governor on March 23, 2018, Chapter 2018-90, Laws of Florida. The bill modifies Section 408.0561, Florida Statutes, to grant an exception from volume requirements for diagnostic cardiac catheterization procedures and ischemic heart disease diagnoses for certain hospitals providing adult cardiovascular services.

The bill expands the type of patients that may be counted to meet the minimum volume threshold for treatment of ischemic heart disease by counting all patients with ischemic heart disease rather than only inpatients. The Lower Keys Medical Center in Key West is the only diagnostic cardiac catheterization program qualifying for this exception.

Controlled Substances

HB 21 was approved by the Governor on March 19, 2018, Chapter 2018-13, Laws of Florida. The bill is intended to address Florida's opioid abuse crisis by expanding the use of the Prescription Drug Monitoring Program ("PDMP"), increasing regulation of prescribers and dispensers, amending criminal laws, and making appropriations. Specifically, the bill:

- Limits the prescription for a Schedule II opioid to alleviate "acute pain" to a three-day supply.
  - A seven-day supply may be prescribed if deemed medically necessary by the prescriber as indicated and documented in the patient's record as "acute pain exception" on the prescription, and must concurrently prescribe an emergency opioid antagonist, as defined in statute.
  - "Acute pain" expressly excludes pain related to cancer, terminal illness, palliative care and serious traumatic injury with an injury severity score of 9 or greater.
  - A health care practitioner is required to review a patient's PDMP history prior to prescribing or dispensing a controlled substance, with exemptions.
  - A prescribing practitioner who is approved to provide medically assisted treatment for opioid addiction is authorized to dispense Schedule II and III substances for such purpose.
- Requires all practitioners authorized to prescribe controlled substances to take two hours of education credits through courses offered by the Florida Medical Association or the Florida Osteopathic Medical Association by January 1, 2019.
- Requires the regulatory boards within the Department of Health ("DOH") to adopt rules establishing guidelines for prescribing controlled substances for acute pain.
- Requires all pain management clinics that claim an exemption from statutory registration requirements to obtain a certificate of exemption by January 1, 2019.
- Requires dispensers to report certain Schedule V drugs to the PDMP, in addition to the current reporting requirement for Schedule II through IV drugs.

- Authorizes certain federal employees who prescribe or dispense controlled substances to have direct access to the PDMP and authorizes indirect access to the PDMP for district medical examiners under certain conditions.
- Authorizes DOH to exchange PDMP data with other states if certain conditions are met, and authorizes the PDMP to interface with electronic health record systems.
- Aligns the state schedule of drugs with the federal schedule of drugs.
- Makes it a crime to possess, purchase, deliver, or sell a tableting machine, encapsulating machine, or controlled substance counterfeiting material for illegally manufacturing controlled substances; and
- Increases the level of offense for health care practitioners who inappropriately prescribe controlled substances from a third-degree felony to a second-degree felony.

For Fiscal Year 2018 through 2019, the bill appropriates $27,035,532.00 in nonrecurring funds from the Federal Grants Trust Fund for substance abuse treatment, recovery, and outreach services; $26,500,000.00 in recurring funds from the General Revenue Fund for substance abuse treatment, outreach services, and upgrades to the PDMP; and $117,700.00 in nonrecurring funds from the General Revenue Fund for upgrades to the PDMP.

Direct Primary Care Agreements

HB 37 was approved by the Governor on March 23, 2018, Chapter 2018-89, Laws of Florida. The bill creates Section 624.27, Florida Statutes, which exempts direct primary care ("DPC") agreements and DPC providers from regulation under the Florida Insurance Code and imposes basic requirements for such agreements.

DPC is a primary care medical practice model that eliminates third-party payers from the primary care provider-patient relationship. Through a contractual agreement, a patient pays a monthly fee, usually between $25.00 and $100.00 per individual, to the primary care provider for defined primary care services, which may also include routine preventative services, women's health services, pediatric care, urgent care, wellness education, chronic disease management, and home visits. The Florida Office of Insurance Regulation does not currently regulate DPC agreements.

Distribution of Pharmaceutical Drugs and Devices

HB 513 was approved by the Governor on March 21, 2018, Chapter 2018-50, Laws of Florida. The bill modifies Section 465.027, Florida Statutes, to exempt third-party logistics providers who distribute dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure from pharmacy permitting requirements. The bill also removes the requirement that a manufacturer or its agent be engaged solely in the manufacture or distribution of dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure to qualify for the exemption.

Third-party logistics providers hold permits issued by the Department of Business and Professional Regulation ("DBPR") to provide supply chain logistics services and transportation for prescription drug manufacturers and distributors. Third-party logistics providers that distribute dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure must

also hold a Special Pharmacy – End Stage Renal Dialysis ("ESRD") permit from the Board of Pharmacy within the Department of Health ("DOH").

Section 465.027(2), Florida Statutes, provides an exemption from pharmacy permitting requirements, including ESRD permits, for a manufacturer, or its agent, licensed by DBPR, engaged solely in manufacturing or distributing dialysate, drugs, or devices necessary to perform home renal dialysis on patients with chronic kidney failure.

Donation and Transfer of Human Tissue

HB 429 was approved by the Governor on March 19, 2018, Chapter 2018-36, Laws of Florida. The bill amends Section 381.0041, Florida Statutes, to require the Department of Health ("DOH") to develop an educational pamphlet to include specified information relating to risks and benefits of human cells, tissue, and cellular and tissue-based product transplants. The pamphlet must, at a minimum, include:

- an overview of the risk of infectious disease transmission;
- an overview of the standards for donor testing and screening;
- an overview of processing methods intended to reduce the risk of disease or bacterial transmission in donated human cells, tissue, or cellular or tissue-based products;
- the importance of providing limited recipient transplant information to the supplier of the human cells, tissue, or cellular or tissue-based product; and
- information about the generosity of the human donor who provided the human cells, tissue, or cellular or tissue-based product.

Once published, DOH is required to electronically notify physicians of the availability of this pamphlet.

Health Care Facility Regulation

HB 622 was approved by the Governor on March 19, 2018, Chapter 2018-24, Laws of Florida. The bill clarifies existing licensure and enforcement requirements, amends certain provisions to eliminate conflict between Part I of Chapter 395, Florida Statutes, Chapter 400, Florida Statutes, and Part II of Chapter 408, Florida Statutes, increases administrative efficiency at the Agency for Health Care Administration ("AHCA"), and repeals redundant or obsolete statutes.

Specifically, the bill:

- repeals the licensure requirements for clinical laboratories;
- repeals the health care risk manager licensure requirements and the Health Care Risk Manager Advisory Council;
- strengthens AHCA's enforcement capabilities for unlicensed assisted living facilities ("ALFs");
- defines the assistance an ALF must provide a resident under the Resident Bill of Rights;
- repeals the Subscriber Assistance Program, which resolves disputes between health maintenance organizations and subscribers;
- repeals the licensure requirements for mobile surgical facilities;

- repeals obsolete special designations of rural hospitals;
- eliminates conflicts and duplicative provisions between Part II of Chapter 408, Florida Statutes, and authorizing statutes;
- repeals the inactive Statewide Managed Care Ombudsman Committee;
- removes language that prevents nurse registries from marketing their services;
- excludes individuals from employment with licensees if they have a pending domestic violence offense and excludes providers from participation in the Medicaid program for criminal offenses including offenses related to the provision of health care services, fraud, and controlled substances;
- establishes requirements for pediatric cardiac programs;
- revises requirements for qualifications for adult cardiac service providers;
- establishes the authority of a county with a public health trust over the trust's facility; and
- makes necessary conforming changes throughout the statutes to reflect the changes proposed in the bill.

Regarding clinical laboratories, the Centers for Medicare & Medicaid Services ("CMS") regulates all laboratory testing (except research) performed on humans in the United States through the Clinical Laboratory Improvement Amendments ("CLIA"). Facilities that provide clinical laboratory services are required to be certified by the CMS CLIA laboratory certification program, which operates in conjunction with the Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"). Certain laboratories may qualify as a waived testing laboratory and receive a CLIA Certificate of Waiver.

Additionally, SB 622 makes the following changes:
Section 91 amends Section 456.054, Florida Statutes, which contains general provisions for healthcare practitioners, to incorporate the clinical laboratory anti-kickback prohibition that was once present in Section 483.245, Florida Statutes, which has been repealed.

Section 97 repeals Part I of Chapter 483, Florida Statutes, relating to the licensure and regulation of clinical laboratories by AHCA. Laboratories will continue to be certified by, or receive a certificate of waiver from, the CMS under the CLIA, as explained above. Included within the repeal is a requirement that laboratory results must be reported directly to the licensed practitioner or other authorized person who requested it, and the authorization for a laboratory to disclose the results without a patient's consent to other health care practitioners and providers involved in the care or treatment of the patient as specified in Section 456.057(7)(a), Florida Statutes.

Section 99 amends Section 483.801, Florida Statutes, to exempt from licensure persons engaged in testing performed by laboratories that are wholly owned and operated by one or more practitioners who are licensed under Florida law as allopathic or osteopathic physicians, chiropractors, podiatrists, optometrists, or dentists and who practice in the same group practice, and in which no clinical laboratory work is performed for patients referred by a health care provider who is not a member of the same group.

Insurance Code Exemption for Nonprofit Religious Organizations

SB 660 was approved by the Governor on March 19, 2018, Chapter 2018-25, Laws of Florida. The bill amends Section 624.1265, Florida Statutes, which governs nonprofit religious organizations that provide health care cost sharing services. It removes the requirement that participants adhere to the same religion, instead allowing participation by individuals "who share a common set of ethical or religious beliefs," which aligns with the federal Patient Protection and Affordable Care Act.

The bill requires nonprofit religious organizations that provide health care sharing services to specify contribution amounts to prospective participants and to report monthly to participants the amount of qualified needs funded in the previous month in accordance with criteria set by the organization. The bill requires these organizations to coordinate an annual audit with an independent certified public accounting firm.

The bill also modifies the standard disclaimer that must be provided by nonprofit religious organizations to prospective participants. The disclaimer indicates that these organizations are not insurers and are exempt from the Florida Insurance Code.

Mammography

HB 735 was approved by the Governor on March 21, 2018, Chapter 2018-59, Laws of Florida. The bill creates Section 381.933, Florida Statutes.

The federal Mammography Quality Standards Act requires mammogram facilities to send each patient a summary of the mammogram report written in lay terms within 30 days of the mammographic examination. The bill codifies the federal requirement that each facility that performs mammography send a summary of a patient's mammography report to each patient. In addition to the federal requirements, if the patient has dense breasts, the bill requires the summary of the mammography report to also include a notice to the patient that the mammogram shows that the patient's breast tissue is dense, which makes it more difficult to detect some abnormalities in the breast and may also be associated with increased risk of breast cancer. However, the bill repeals this statutory requirement effective June 30, 2023.

Medication Administration

HB 1373 was approved by the Governor on March 23, 2018, Chapter 2018-107, Laws of Florida. The bill modifies Section 393.506, Florida Statutes, which allows trained but unlicensed personnel to provide or supervise eight routes of medication administration (enteral, inhaled, ophthalmic, oral, otic, rectal, topical, and transdermal) to clients.

The bill revises the training and validation requirements for unlicensed personnel to administer or supervise self-administration of medication in Agency for Persons with Disabilities (“APD”) facilities by:

- increasing the length of the initial training course from four to six hours;

- adding an annual requirement of two hours of in-service training in medication administration and error prevention, which can count towards existing in-service training requirements;
- eliminating the annual revalidation requirement for otic, transdermal, and topical routes of medication administration;
- requiring initial validation by simulation during the initial training course rather than on an actual client for otic, transdermal, and topical routes of medication administration;
- grandfathering certain unlicensed personnel already trained and validated to administer medication; and
- requiring retraining for certain unlicensed personnel who lapse in their training requirements.

Currently, only a registered nurse or physician may train and validate unlicensed personnel. The bill allows a licensed practical nurse to train and validate unlicensed personnel. The bill grants the APD rulemaking authority to establish qualification requirements for trainers and enforce the provisions of Section 393.506, Florida Statutes.

Nursing Nomenclature

HB 1137 was approved by the Governor on March 23, 2018, Chapter 2018-106, Laws of Florida. The bill amends multiple chapters of the Florida Statutes to update nursing qualifications. The bill changes the term "advanced registered nurse practitioner" to "advanced practice registered nurse" (“APRN”) throughout Florida Statutes. This conforms Florida laws to those in a majority of states.

Advanced registered nurse practitioners (“ARNPs”) are licensed registered nurses with post-graduate education in nursing that prepares them to perform advanced or specialized nursing. ARNPs may perform nursing acts, or medical acts authorized by a written protocol with a physician. A clinical nurse specialist (“CNS”) is trained in a specialized area, such as a certain population, setting, or disease state. Both ARNPs and CNSs receive advanced training; however, the two professions require separate certifications.

The bill repeals the separate certification for a CNS and instead incorporates CNS into the category of APRN. The bill retains the current scope of practice of a CNS but requires a CNS to practice pursuant to a written protocol with a physician.

Currently, APRNs are licensed as registered nurses and then certified as APRNs. The bill authorizes the Department of Health (“DOH”) to license, rather than certify, APRNs as such. The bill also adds the category of "certified nurse practitioner" to APRN, which is comprised of the same group of licensees who are currently termed "nurse practitioners."

The bill requires DOH and the Board of Nursing to develop a transition plan to convert the certifications that ARNPs and CNSs currently hold to licenses as APRNs. The bill authorizes currently certified ARNPs and CNSs to continue practicing under such certifications until DOH and the Board of Nursing complete the transition from certification to licensure.

Perinatal Mental Health

HB 937 was approved by the Governor on March 23, 2018, Chapter 2018-98, Laws of Florida. The bill creates Section 383.314, Florida Statutes, and amends Section 383.318, Florida Statutes. The bill requires the Department of Health ("DOH") to provide perinatal mental health information through its Family Health Line toll-free hotline. The bill requires the hotline to provide basic information on postpartum depression and authorizes hotline operators to recommend that a caller be further evaluated by a qualified health care provider or refer a caller to an appropriate health care provider in the caller's local area.

The bill requires birth centers to provide a mental health screening and information on postpartum depression, including the telephone number of the Family Health Line, as components of postpartum evaluation and follow-up care.

The bill appropriates $104,320.00 recurring General Revenue funds and $21,600.00 nonrecurring General Revenue funds to DOH to implement the provisions in the bill.

Pharmacies

HB 675 was approved by the Governor on March 23, 2018, Chapter 2018-95, Laws of Florida. The bill amends multiple provisions in Chapters 465 and 499, Florida Statutes.

The Department of Health ("DOH") issues three types of institutional pharmacy permits for every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. Institutional pharmacy permit holders must also obtain additional permits from the Department of Business and Professional Regulation ("DBPR") to distribute drugs. Entities that operate multiple permitted institutional pharmacies must obtain permits from DBPR for each of its permitted locations.

Section 340B of the federal Public Health Services Act requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities, including certain types of hospitals, at significantly reduced prices to serve primarily low income and vulnerable populations.

The bill creates a Class III institutional pharmacy permit ("Class III permit") for hospital-affiliated institutional pharmacies, including central distribution facilities, which provide the same services authorized by a Class II permit. The bill exempts Class III permit holders from obtaining additional permits from DBPR to distribute medical drugs or prepackaged drug products between certain entities under common control. The bill also exempts hospitals that participate in the Section 340B Drug Discount Program from obtaining a permit from DBPR when arranging for a prescription drug wholesale distributor to distribute prescription drugs covered by the Section 340B Drug Discount Program directly to its contract pharmacy.

Pregnancy Support and Wellness Services

HB 41 was approved by the Governor on March 19, 2018, Chapter 2018-29, Laws of Florida, and creates Section 381.96, Florida Statutes, thereby codifying the Florida Pregnancy Support Services Program ("FPSSP") and defining program requirements.

The FPSSP was established by the budget through proviso in 2005 to provide pregnant women and their families supportive counseling and services that promote and encourage childbirth. Under contract with the Department of Health ("DOH"), the Florida Pregnancy Care Network, Inc., ("FPCN"), manages a network of pregnancy help centers that offer services such as pregnancy testing, counseling, education and training, and referrals to state, community, and medical resources.

The bill requires DOH to contract with FPCN to provide contract management services for the delivery of pregnancy support services to pregnant women and their families and wellness services to women, regardless of pregnancy. The contract must:

- require FPCN to establish and manage subcontracts with a sufficient number of providers to ensure the availability of pregnancy support and wellness services for eligible clients;
- limit the amount of funds that may be used for administration;
- require all paid staff or volunteers of a provider to undergo a background screening if they provide direct services to minors, elderly individuals, or individuals who have a disability;
- require FPCN to monitor its subcontractors annually, and establish sanctions for noncompliance;
- require FPCN to only subcontract with providers that solely promote and support childbirth;
- require informational materials provided to eligible clients be current and accurate, and the reference source of any medical statements made in such materials be made available to eligible clients; and
- define the contract deliverables, including financial reports and other reports due to DOH.

The bill requires that any services provided under FPSSP be provided in a non-coercive manner and not include any religious content.

Prescription Drug Pricing Transparency

HB 351 was approved by the Governor on March 23, 2018, Chapter 2018-91, Laws of Florida. The bill amends Section 464.0244, Florida Statutes, repeals Section 465.1862, Florida Statutes, and creates Sections 624.490, 627.64741, 627.6572 and 641.314, Florida Statutes.

The bill requires pharmacy benefit managers ("PBMs") that conduct business in Florida to register with the Florida Office of Insurance Regulation ("OIR") by submitting identifying organizational information, an application, and a fee. The bill requires that a contract between a PBM and a health insurer or a health maintenance organization ("HMO"):

- include prohibitions on certain practices that limit patient access to pricing information;
- require the PBM to update maximum allowable cost pricing information at least once every seven days; and

- limit patient cost sharing for a drug to the lesser of the applicable cost sharing amount or the retail price.

The bill authorizes OIR to enforce these requirements upon health insurers and HMOs that apply to contracts entered or renewed on or after July 1, 2018.

The bill also creates an affirmative duty for a pharmacist or authorized employee to communicate to a patient the availability of a lower cost, generically equivalent drug and whether the patient's cost-sharing obligation exceeds the retail price of a drug in the absence of prescription drug coverage.

Public Records/Public Guardians/Employees with Fiduciary Responsibility

SB 268 was approved by the Governor on March 19, 2018, Chapter 2018-16, Laws of Florida. The bill creates Section 744.21031, Florida Statutes, which creates a public records exemption for the identifying and location information of current and former public guardians, employees with fiduciary responsibilities, and their spouses and children. Additionally, the bill exempts the places of employment of spouses and children of these personnel and the names and locations of schools and day care facilities attended by the children of those persons. The bill requires any agency that is the custodian of the information specified above to maintain the exempt status of that information upon the written request of a current or former public guardian or employee with fiduciary responsibility.

Public guardians act on behalf of indigent incapacitated persons who are unable to manage their own affairs and lack family members, friends, other persons, banks, or corporations willing and qualified to serve as their guardians.

The bill provides for retroactive application of the public record exemption and includes a statement of public necessity as required by the Florida Constitution. The bill also requires repeal of the exemption on October 2, 2023, unless reviewed and saved from repeal through reenactment by the Legislature.

Submitted By: Jan J. Gorrie, Esq., Of Counsel, Panza, Maurer & Maynard, P.A.

PRIVACY UPDATES

Judge Rules OCR HIPAA Penalties of $4.3 Million Were Reasonable

The Department of Health and Human Services, Office of Civil Rights ("OCR") investigated MD Anderson Cancer Center for three events that occurred between April 2012 and November 2013 involving the electronic protected health information ("ePHI") of 33,500 patients. Each event involved the loss or theft of unencrypted devices. At the close of the investigation, the OCR recommended a civil monetary penalty of $4,348,000.00. MD Anderson disagreed with the decision and filed an appeal.

MD Anderson argued that it was not required to encrypt its devices because the ePHI at issue was for research and therefore not subject to HIPAA nondisclosure requirements, the loss of an unencrypted device is not a disclosure unless someone views the data, it should not be liable for its employees who are not following policies, and that the penalties imposed against it were unreasonable. Both parties moved for summary judgment and on June 1, 2018, the Administrative Law Judge granted the OCR's motion for summary judgment finding that:

- MD Anderson was required to encrypt its devices because it had recognized that encryption was necessary to protect ePHI as early as 2006 and had instituted polices requiring encryption.
- The loss or theft of an unencrypted device is a "disclosure."
- The argument that HIPAA does not apply because the information was for research was without merit.
- The fact that employees may not have been following policy does not put their actions outside the scope of employment.
- The penalties were reasonable.

The OCR and the judge agreed that MD Anderson's violations met the "reasonable cause" or second tier of penalties. "Reasonable cause" is defined at 45 C.F.R. § 160.401 to mean "an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect."

The second tier allows penalties ranging from $1,000.00 to $50,000.00 for each violation with a cap of $1,500,000.00 for identical violations committed during a calendar year. The OCR argued that each day that MD Anderson failed to encrypt ePHI was a separate violation and sought to impose $2,000.00 per day per penalty for the period from March 24, 2011 until January 26, 2013, and the maximum of $1,500,000.00 per year to remedy the loss of ePHI for 31,000 individuals in 2012 and more than 35,000 individuals in 2013.

The judge agreed and held that MD Anderson was noncompliant on each day of the period at issue and that the penalties were reasonable given the level of MD Anderson's culpability. The judge also noted that it was reasonable to count the loss of ePHI for each affected individual as a separate violation. Finally, the judge denied MD Anderson's arguments that the penalties were excessive, noting "[w]hat is most striking about this case is that Respondent knew for more than five years that its patients' ePHI was vulnerable to loss and theft and yet, it consistently failed to implement the very measures that it had identified as being necessary to protect that information."

Submitted by: Patricia Calhoun, Esq., Carlton Fields

OCR Issues New Interim Guidance on Sufficient Descriptions of a Use or Disclosure of PHI for Future Research Authorizations under HIPAA

In June 2018, the Secretary of the Department of Health and Human Services, Office for Civil Rights ("OCR") issued new Guidance related to streamlining authorization under HIPAA for uses and disclosures of protected health information ("PHI") for future research.[21] The Privacy Rule

(45 C.F.R. Part 160 and Subparts A and E of Part 164) allows covered entities and business associates to use and disclose PHI only as permitted or required by the Privacy Rule or as authorized by an individual. Although exceptions exist allowing the limited use and disclosure of PHI for research without an individual's authorization, the recent Guidance focused on situations in which an entity is required to obtain an authorization from an individual to use and disclose the individual's PHI for future research purposes. OCR states that a description of future research purposes is compliant with 45 C.F.R. § 164.508(c)(1)(iv) "if the description sufficiently describes the purposes such that it would be reasonable for the individual to expect that the protected health information could be used or disclosed for such future research." However, it is important to note that OCR qualified the above-mentioned statement as "Interim Guidance" and is currently seeking additional insight and input on the question of "what constitutes a sufficient description such that it would be reasonable for the individual to expect that the PHI could be used or disclosed for such research." The Guidance also provided clarification on expiration of authorizations for future research and the right to revoke authorizations.[22]

Submitted by: Zachary Merson, Esq., Availity, LLC

TRANSACTIONS UPDATES

The State of the Dental Market

It is estimated that the market for dental services is approximately $123 billion dollars.[23] Over the past three to five years, patients over the age of 65 have significantly utilized more dental services than patients under the age of 65.[24] The increased demand for dental services, combined with the reduced risk related to reimbursement for dental services, has spiked interest and activity in the dental market by private equity and strategic investors.[25]

According to one report, dental support organizations ("DSO") only own 16% of total practices in the United States which makes the potential for growth a perfect fit for private equity.[26] There are many dental transactions (further detailed in the article cited herein) and those buyers use either a dental practice management model ("DPM") or a DSO model.[27] The DPM model allows private equity to invest in a dental management company without investing in the dental practice by providing all of the administrative services without billing and collections (except for claims).[28] This also makes it an attractive model for practitioners.[29]

Examples of private equity and strategic investments are further described in the article and include Heartland Clinic, Smile Doctors and Dental Partners (Melbourne, Florida based).[30] Finally, there are numerous regulatory considerations involved in any dental transaction including corporate practice of dentistry, compliance and ancillary services that must be carefully navigated.[31] However, there is a strong suggestion that opportunities for consolidation exist for investors willing to navigate those regulatory challenges.[32]

Submitted By: Anushree ("Anu") Sagi-Nakkana, Esq., ASN Law Firm

[1] FLA. ADMIN. CODE r. 64B9-8.005(13).
[2] No. 18-000504PL (Fla. DOAH May 25, 2018) (Recommended Order).
[3] *Id.* at 7.
[4] *Id.* at 8.
[5] *Id.* at 9.
[6] *Id.*
[7] *Id.* at 12.
[8] *Id.* at 14.
[9] *Id.*
[10] *Id.* at 17-18.
[11] "Medicare Program; Request for Information Regarding Physician Self-Referral Law (Proposed Rule)," 83 Fed. Reg. 29524 (June 25, 2018).
[12] 42 U.S.C. § 1395nn.
[13] "CMS seeks public input on reducing regulatory burdens of the Stark Law," CMS.GOV (June 20, 2018), *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-06-20-2.html.
[14] *See* "Statement of the American Hospital Association before the Subcommittee on Health of the Committee on Ways and Means of the U.S. House of Representatives," AHA.ORG, (Mar. 21, 2018), *available at* https://www.aha.org/system/files/2018-03/180321-macra-statement-house-ways-means.pdf.
[15] *See Complaint & Demand for Jury Trial, Am. College of Emerg. Physicians & Med. Assoc. of Ga. v. Blue Cross & Blue Shield of Ga. & Anthem Ins., Inc.*, No. 1:18-cv-03414-MLB, 2018 WL 3453477 (N.D. Ga, July 17, 2018).
[16] 42 U.S.C. § 1395dd.
[17] *Id.* § 18166, et seq.
[18] 29 U.S.C. § 1132(a)(1)(B), et seq.
[19] 42 U.S.C. § 2000D, et seq.
[20] Regulatory changes include: "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program Final Rule (83 FR 16440)," *available at*: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-07179.pdf; and the "Announcement of Calendar Year 2019 MA Capitation Rates and MA/PD Payment Policies and Final Call Letter," *available at*: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf. The important legislative change was enacted through the Bipartisan Budget Act of 2018 (H.R. 1892), *available at*: https://www.congress.gov/bill/115th-congress/house-bill/1892/text.
[21] "Research" is defined in the Privacy Rule as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." 45 C.F.R. § 164.501.
[22] A copy of this Guidance is available at: https://www.hhs.gov/sites/default/files/hipaa-future-research-authorization-guidance-06122018%20v2.pdf.
[23] Kayla McCann Marty, *An Insider's View of the State of the Dental Market*, Bender's Health Care Law Monthly (Apr. 1, 2018).
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.*
[31] *Id.*
[32] *Id.*