April 2020

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with February through March 2020 articles on significant developments in the health law arena that may be of interest to you in your practice. This edition is unique in that many of the articles focus on the recent COVID-19 pandemic affecting the nation. As a result, we have divided this edition into COVID-19-related articles versus non-COVID-19 related articles, with the former appearing at the beginning of this publication. We also recognized that some of these articles may discuss overlapping topics, but the Editors believed these issues are significant enough to include various perspectives. Please note that the laws are changing on an almost-daily basis. As such, some of these Updates may no longer be entirely accurate by the time these Updates are published or reviewed. We recommend that our readers consult applicable legal authorities to evaluate whether the information summarized herein is still accurate upon reading these Updates.

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

- **Audrey Davis, Esq., Elizabeth Scarola, Esq., & Kathleen Premo, Esq., *Epstein Becker & Green, P.C.***
- **Barbara L. Kornblau, Esq., *Law Office of Barbara L. Kornblau* and *Coalition for Disability Health Equity***
- **Colby J. Ellis, Esq., *Johnson Jackson PLLC***
- **William Gamble, JD, LLM, CASP, *CompTIA Advanced Security Practitioner***
- **Angelina Gonzalez, Esq., *Panza, Maurer, & Maynard, P.A.***
- **Amy Morse, Esq., *Morse & Morse, LLC***
- **Jeffrey Mustari, Esq., *Southern Health Lawyers, LLC***
- **Amanda Newlon, Esq., *Shumaker, Loop & Kendrick, LLP***
- **Nicole M. Perez, J.D., Government & Legislative Relations Manager, *Florida Blue***
- **Tadena Simpson, Esq., Senior Counsel, *Envision Rx Options***
- **Jessica Weissman, PhD, RDN, LDN, Program Director and University Department Chair at Keiser University, Melbourne**
- **Sam Winikoff, Esq., *Beighley, Myrick, Udell & Lynne, P.A.***

Thank you,

Jamie Gelfman, Esq., *Nelson Mullins Broad and Cassel*, HLS Editor in Chief

Ashley Brevda, Esq., Corp Counsel/Chief Compliance Officer, *Oncology Analytics, Inc.*, HLS Team Editor

Trish Huie, Esq., *Patricia A. Huie, PLLC*, HLS Team Editor

TABLE OF CONTENTS

COVID-19:
COMPLIANCE UPDATES
Infection Control

CMS & CDC Infection Control and Prevention Guidance for Hospitals and Nursing Homes

The Centers for Disease Control and Prevention ("CDC") and Centers for Medicare and Medicaid Services ("CMS") and have recently taken steps to combat the spread of infectious disease amid the mounting threat to public health presented by the novel coronavirus (COVID-19) pandemic.

The CDC maintains, and continually updates, online resources that provide current information and instructions for healthcare providers with respect to responding to COVID-19. The CDC website includes, for instance, guidance regarding healthcare facilities' imposition of restrictions on visitation, implementation of rules on patient discharge, and treatment obligations under the Emergency Medical Treatment and Labor Act ("EMTALA"). Additionally, the guidance grants some leeway on noncompliance due to the inability to obtain certain medical supplies in instances where such shortages are beyond the control of the entity.

On March 4, CMS announced that, effective immediately and until further notice, it would suspend non-emergency state survey inspections to focus on compliance with infection control protocols. This suspension will not apply to inspections prompted by complaints indicating potential immediate jeopardy, abuse, neglect, or infection control concerns or to inspections mandated by law, preexisting enforcement action that is ongoing, or those statutorily required as part of a certification process.

CMS has since issued a number of guidance memoranda specifically addressing issues raised by COVID-19 that healthcare entities may encounter in in responding to COVID-19, either through treatment of those infected, preventing its spread, or both. These issues include screening patients for COVID-19; isolating those with confirmed or suspected cases of it; implementing protocols to prevent spread, triage, discharge planning; complying with obligations under EMTALA; addressing resource shortages; and following individualized guidance for hospitals, nursing homes, home health agencies, hospice agencies, and dialysis providers.

While CMS regulates any health care provider enrolled in Medicare, those most significantly affected by the new CMS guidance will be hospitals and nursing homes. Hospitals are affected because EMTALA applies to any facility with an emergency department and because issues related to patient discharge only affect in-patient facilities. Nursing homes will be affected because of the heightened vulnerability of the elderly population of nursing home residents, combined with the heightened risk of spread of disease in communal living facilities, which has led CMS to impose very strict rules limiting outside contact with nursing home residents.

Hospitals

CMS directs hospitals to check the CDC website regularly and follow all guidance issued by the CDC. In particular, CMS calls for hospitals to screen all patients and visitors upon arrival for indicators of potential COVID-19 infection and to implement respiratory hygiene and cough etiquette measures. This screening process consists of asking individuals about: (1) COVID-19 symptoms; (2) recent international travel to certain countries: and (3) contact with individuals known or suspected to be infected with COVID-19. Patients identified as at risk of being infected are to be separated to the extent feasible (at the very least six feet away from other patients) and provided with respiratory hygiene supplies and instruction, and the facility should notify public health authorities and staff of the possible infection. CMS also instructs hospitals to screen staff using the same process and direct those at risk to self-isolate at home.

CMS special COVID-19 guidance on EMTALA obligations makes clear that the threat of infection does not relieve facilities of the requirement to perform a medical screening examination on any patient that presents to the Emergency Department. It does, however, explicitly authorize setting up alternative, on-campus screening sites so as to better separate patients. The guidance provides specific instructions on how to do this in a way that complies with EMTALA. The guidance also addresses the issue of whether a particular facility has the capability to treat patients with COVID-19. CMS defers to the latest CDC guidance on infection control and treatment regarding capability, but CMS does clearly state that lack of specialized isolation facilities alone will not be sufficient grounds to avoid the EMTALA duty to provide treatment to COVID-19 patients suffering from an emergency medical condition.

If a hospital admits a patient covered by Medicare, it must follow CMS regulations governing patient discharge. Medicare's Discharge Planning Regulations require hospitals to assess the patient's needs for post-hospital services, and the availability of such services prior to discharge. CMS guidance states that hospitals must communicate to post-discharge healthcare providers that a patient was treated for COVID-19 as part of the discharge planning process.

CMS's COVID-19 guidance also states that hospitals must inform patients of their rights regarding visitation and any limitations or restrictions that are placed on visitation.

Nursing Homes

CMS issued a memorandum on infection control in nursing homes that calls for severe restrictions on nursing homes in an effort to safeguard one of the populations most vulnerable to COVID-19. The guidance directs nursing homes to prohibit all non-essential outside individuals from entering the facility, including volunteers and providers of non-essential services such as barbers. This prohibition applies to all visitation as well, except in certain compassionate care situations, such as an end-of-life situation, in which case the visitor's movement is limited to the room of the resident being visited, and he or she must utilize personal protective equipment ("PPE"). Furthermore, would-be visitors exhibiting signs of respiratory infection are barred entrance to nursing homes *even in end-of-life situations*. The new guidance also directs nursing homes to implement active COVID-19 screening of staff and residents and to cancel group activities and communal dining.

The CMS nursing home memorandum provides nursing home administrators with assistance in dealing with difficult realities created by the COVID-19 outbreak, including specific instructions on how to approach decisions regarding transfer and admission of infected or potentially infected individuals, and granting a temporary exemption from enforcement of rules requiring nursing homes to have certain supplies that have become scarce. This exemption only applies if: (1) the facility is unable to obtain the supplies due to circumstances outside of its control; (2) it is taking reasonable steps to secure the supplies as soon as reasonably possible; and (3) reasonable work-around measures have been implemented to mitigate the effects of the absence of the unavailable supplies.

Submitted by: **Jeffrey Mustari, Esq., Southern Health Lawyers, LLC, a Sanders & Mustari Law Firm**

COVID-19:
DATA SECURITY UPDATES
Cyberattacks

Cyber Criminals Look to Exploit COVID-19 for Financial Gain

While there are many businesses negatively impacted by the COVID-19 pandemic, the business of hacking isn't one of them. Hackers look forward to disasters because they can use the increased fear as motivation to fall for the most recent scam.

Cyber criminals have been taking advantage of the recent prominence of the World Health Organization ("WHO") and the United States Center for Disease Control and Prevention ("CDC") to create fraudulent websites. These websites and clones try various activities to turn a victim's anxiety into cash. They advertise everything from antiviral cures or equipment to impossible-to-get face masks, hand sanitizers and ventilators all of which turn out to be fake. These criminals also solicit funds in the form of bitcoins, proclaiming such funds to be for vaccine research.

Nation state actors are also involved. According to U.S. State Department official Lea Gabrielle in testimony before Congress, Russia was responsible for "swarms of online, false personas" that were spreading misinformation about the disease. She stated that the "entire ecosystem of Russian disinformation is at play" in attempts to capitalize on uncertainty caused by the pandemic. Along those lines, the U.S. Department of Health and Human Services was recently hit by a cyberattack.

Hospitals and healthcare facilities have also been specifically targeted. The Czech Republic's second-biggest hospital, the Brno University Hospital, was recently hit by a cyberattack. The hospital was fortunate not to have to shut down, but it would be easy to imagine the enormous pressure to quickly pay a ransom to get crucial services back in desperate times.

Hackers are also taking advantage of new telecommuters. In office settings, security departments can have a high degree of control over the network and the environment. This may not be the case for workers at home.

While it is impossible for all workers, or even the well informed, to be aware of the myriad of types of cyberattacks, there are three main areas where they have exploited victims with the most success:

(1) Social Engineering
(2) Passwords
(3) Unpatched systems

Social Engineering. This is the most important area for telecommuters. It is also an area where, with sufficient training, staff can avoid problems. This is also required under HIPAA's administrative safeguards regulations.[1]

Passwords. The second area relates to passwords. Problems corresponding to passwords can be solved by adhering to a few practical rules. Staff should use passphrases that are potent and easy to remember, and should be sure to use different passphrases for different accounts. Password

managers are both convenient and impressive. Wherever possible firms should institute two-factor or multifactor authentication ("MFA"). Access control is also required under the HIPAA regulations.[2]

Unpatched systems: The third area has to do with ensuring that any technology that staff is using is using the most up-to-date version. Unpatched applications can be hacked within 48 hours after a patch comes out or a vulnerability is publicized.

There are several other areas that may need consideration depending on a business's specific priorities. For example, these may include VPNs, device use by family, working while traveling, and WiFi hygiene. These areas are further discussed on the SANS information security institute website.[3]

New telecommuters can introduce substantial cyber security risks into a system, but with the proper precautions, including many controls listed in the ISO 27001 and other frameworks,[4] the risk of economic fallout resulting from a hack during the COVID-19 pandemic may be mitigated.

Submitted by: **William Gamble, JD, LLM, CASP, *CompTIA Advanced Security Practitioner***

COVID-19:
LEGISLATIVE UPDATES
Coronavirus Aid, Relief, and Economic Security (CARES) Act

CARES Act Modernizes Confidentiality & Use of Substance Use Disorder Patient Records

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, a $2 trillion measure designed to respond to the COVID-19 ("coronavirus") pandemic, was signed into law (the "Act"). It is largest economic stimulus package in American history. Some of the Act's more sweeping provisions have been widely publicized over recent weeks, including its direct payments and jobless benefits for individuals and a bailout fund with billions in aid meant for large and small businesses. However, a much-less recognized part of the legislation is poised to have a major impact on addiction treatment providers and confidentiality of patient records.

Prior to passage of the Act, there was a movement over the past several years to modernize federal law governing the confidentiality and use of substance use disorder ("SUD") patient records (which is referred to collectively as "Part 2")[5] with HIPAA. The Act surpasses the 2017 revisions and 2019 proposed rule changes to Part 2 to more closely conforms these regulations the HIPAA Privacy and Security Rules. The Act also adds heightened protections and penalties for use of SUD records in criminal and legal proceedings, as well as specific anti-discrimination protections.

The most significant changes ease a provider's current Part 2 disclosure restrictions. With few exceptions, Part 2 requires patient consent or court order before SUD patient records can be disclosed to any third party. Also, any party who receives SUD patient records, even with patient consent, cannot re-disclose this information to any other party without specific consent to do so, by court order, or under narrow circumstances set forth in the law (such as in medical emergencies). On the other hand, under the HIPAA Privacy Rule, patient records can be disclosed, even without consent, for treatment, payment, and healthcare operations activities (subject to specific state law). For example, under HIPAA, a provider may use protected health information to consult with other providers about an individual's treatment and for billing purposes, and re-disclosure of that information would be permitted for similar purposes.

Unlike HIPAA, the new legislation still requires consent for disclosure of SUD records. However, only one consent for initial disclosure will now be required for treatment, payment, and healthcare operations purposes, and after such disclosure, subsequent disclosures will be able to be made unless and until the patient revokes his or her consent. This alignment with HIPAA's Privacy Rule should provide for greater access to and efficiency in payment for healthcare services for those seeking addiction treatment. The CARES Act also aligns Part 2 more closely with HIPAA in several other ways, including with respect to the Breach Notification Rule, notice and privacy practices, and accounting of disclosures.

Finally, the CARES Act also adds significant anti-discrimination protections for patients. These new provisions prohibit discriminating against any individual based on the information in addiction treatment records, including in admission to healthcare services, employment, or in housing service.

Most importantly, unlike many other changes that were implemented as a result of the CARES Act, these modifications to Part 2 are permanent in nature. Though the changes to Part 2 did not come in a way that anyone could have predicted, many who have long sought these reforms are grateful that this sweeping legislation took these important patient privacy matters into consideration.

Submitted by: **Sam Winikoff, Esq.,** ***Beighley, Myrick, Udell & Lynne, P.A.***

COVID-19:
LEGISLATIVE UPDATES
Families First Coronavirus Response Act

UPDATED: The Definition of "Health Care Provider" under the Families First Coronavirus Response Act Creates Uncertainty[6]

The Families First Coronavirus Response Act ("FFCRA"), which was signed into law on March 18, 2020, requires covered employers to provide eligible employees with leave benefits if they meet certain criteria. However, the law provides that employers of emergency responders and "health care providers" may exclude these types of employees from FFCRA leave benefits. The Department of Labor ("DOL") instituted a temporary rule, effective April 2, 2020 through December 31, 2020, that greatly expands and clarifies the definition of a "health care provider" under the FFCRA.[7] Notably, to minimize the spread of COVID–19, the DOL encourages employers to be judicious when using the definition of health care provider to exclude employees from the provisions of the FFCRA.

Under the DOL's new rule, the definition of health care provider whom employers may elect to exclude from the leave benefits is very broad. Health care providers include anyone employed at any doctor's office, hospital, health care center, clinic, post-secondary educational institution offering health care instruction, medical school, local health department or agency, nursing facility, retirement facility, nursing home, home health care provider, any facility that performs laboratory or medical testing, pharmacy, or any similar entity. Employees of any permanent or temporary institution, facility, location, or site where similar medical services are provided are also considered health care providers. The definition of health care provider further encompasses any employee of an entity that contracts with any of the foregoing institutions to provide services or to maintain the operation of the facility where that employee's services support the operation of the facility. This also includes employees of any entity that provides medical services, produces medical products, or is otherwise involved in the making of COVID-19 related medical equipment, tests, drugs, vaccines, diagnostic vehicles, or treatments. Additionally, the rule allows the highest official of a state or territory to expand the definition even further to include any individual that the highest official determines is a health care provider necessary for that State's or territory's or the District of Columbia's response to COVID-19.

It is important to note that the definition of health care provider applies only for the purposes of determining whether an employer may elect to exclude an employee from the provisions of the FFCRA. For other purposes under the FFCRA, such as determining which health care providers may certify an employee's need to self-isolate or quarantine, the limited definition of health care provider as specified under the FFCRA and FMLA will apply.

Finally, because an employer of a health care provider is not required to exercise the exclusion option, if an employer does not elect to exclude an otherwise-eligible health care provider from using the FFCRA leave benefits, such leave is subject to all other requirements of those laws and accompanying regulations, and should be treated in the same manner for purposes of the tax credit created by the FFCRA. If an employer violates the FFCRA, including fines, imprisonment,

damages to the employee amounting to double the unpaid wages, and reasonable attorney's fees and court costs.

Submitted by: **Amanda Newlon, Esq., *Shumaker, Loop & Kendrick, LLP***

COVID-19:
LEGISLATIVE UPDATES
Families First Coronavirus Response Act

Some Health Care Employers May Elect to be Exempt from New Paid Leave Requirements under FFCRA

On Wednesday, March 18, 2020, President Donald J. Trump signed into law the Families First Coronavirus Response Act (the "Act").[8] This Act has two major components that affect some employers: (1) the Emergency Paid Sick Leave Act ("EPSLA"); and (2) the Emergency Family and Medical Leave Expansion Act ("EFMLEA"), both of which can require an employer to provide paid leave to employees.[9] Both the EPSLA and EFMLEA, however, provide special rules for employers who employ health care providers and emergency responders as employees.[10] Under these special rules, such employers may elect to exempt health care providers or emergency responders from receiving any paid leave made available under the EPSLA and EFMLEA.[11]

If such an employer does not elect to be exempt, then they must comply with the new paid leave requirements unless the Secretary of Labor issues regulations excluding certain health care providers or emergency responders from receiving the newly available paid leave. The new paid leave requirements under the EPSLA and EFMLEA are summarized below.

EPSLA:

Under the EPSLA, covered employers must provide paid sick leave if an eligible employee takes the leave for a qualifying reason.[12] An eligible employee can use the paid sick leave if he or she is unable to work (or telework) due to a need for leave because: (1) he or she is subject to a federal, state, or local quarantine or isolation order related to COVID-19; 2) he or she has been advised by a health care provider to self-quarantine due to concerns related to COVID-19; (3) he or she is experiencing symptoms of COVID-19 and is seeking a medical diagnosis; (4) he or she is caring for an individual who is subject to an order as described in #1 or has been advised as described in #2; (5) he or she is caring for a son or daughter if the son or daughter's school or place of care has been closed, or the childcare provider of such son or daughter is unavailable, due to COVID-19 precautions; or (6) he or she is experiencing any other substantially similar condition specified by the Secretary of Health and Human Services in consultation with the Secretary of Treasury and the Secretary of Labor.[13]

An eligible employee is any employee of a covered employer, and the paid leave is immediately available.[14]

The EPSLA defines a covered employer as: (1) any private-sector entity or individual that employs fewer than 500 employees; and (2) any public agency or any other entity that is not a private entity or individual, which employs one or more employees.[15]

If an eligible employee has a qualifying reason as described above, then the covered employer must provide that employee paid sick leave in the amount of 80 hours if the employee is full-time,

or a number of hours equal to the number that such an employee works, on average, over a two (2)-week period if the employee is part-time.[16]

If the employee takes the leave for their own required quarantine or isolation or to seek a diagnosis while experiencing symptoms, the covered employer must pay the sick leave at the greater of either the employee's regular rate of pay, the federal minimum wage, or the minimum wage of the state or locality. In this case, pay is capped at $511.00 per day and $5,110.00 in the aggregate for an individual employee.[17] If the employee takes the leave to care for an individual who is under quarantine, to care for a son or daughter due to a closure of a school or child care due to COVID-19, or another qualifying reason, then the required compensation shall be two-thirds of the amount described above. In this case, pay will be capped at $200.00 per day and $2,000.00 in the aggregate for an individual employee.[18]

EFMLEA:

The EFMLEA expands the Family and Medical Leave Act ("FMLA") by adding another qualifying reason for leave to those already available under the FMLA.[19] That qualifying reason involves the need to care for a son or daughter due to the closure of a school or child-care provider in the COVID-19 public emergency.[20] With respect to this reason for leave, the expansion makes three changes to the FMLA: (1) it modifies the definition of a covered employer; (2) it lowers the threshold of service time needed for employee eligibility; and (3) it requires a portion of the leave to be paid. All other provisions of the FMLA remain in effect.

Under the EFMLEA, a covered employee is any private-sector or public-agency employer with at least one but fewer than 500 employees.[21] These covered employers must provide FMLA leave to an eligible employee to the extent he or she requests it for the added qualifying reason and has FMLA leave available or remaining. Any employee who has worked for a covered employer for at least 30 calendar days is eligible to take FMLA leave for the added qualifying reason.[22]

If a covered employer provides an eligible employee FMLA leave for the added qualifying reason, then a portion of it must be paid.[23] The first ten (10) days can be unpaid, but the employee can elect to substitute any accrued paid vacation, personal, or sick leave.[24] The remaining FMLA leave taken for the added qualifying reason must be paid at a rate that is not less than two-thirds of an employee's regular rate of pay.[25] That rate must be multiplied by the number of hours that the employee would otherwise be normally scheduled to work.[26] This paid leave is subject to a $200.00 daily and $10,000.00 aggregate cap per employee.[27]

Submitted by: **Colby J. Ellis, Esq., *Johnson Jackson PLLC***

COVID-19:
REGULATORY UPDATES
Agency Guidance

Tackling the COVID-19 Crisis: A Primer for Health Plans

The past few weeks have been rife with panic and stress as individuals across the nation have been forced to face a myriad of uncertainties with the latest pandemic – the Coronavirus or COVID-19. Given its rampant spread and lack of any specific antiviral treatment or vaccine to protect against the virus, several federal and state agencies have stepped in with directives and guidance for combating the spread of COVID-19, including the Centers for Medicare and Medicaid Services ("CMS") and the Florida Office of Insurance Regulation ("OIR"). This article will summarize the memoranda and recommendations that CMS and OIR have issued to plan sponsors and health insurers regarding COVID-19.

I. CMS Guidance to Plan Sponsors

On March 10, 2020, CMS published a memorandum advising Medicare Advantage ("MA") and Part D plan sponsors of their "obligations and permissible flexibilities related to disasters and emergencies resulting from COVID-19."[28] The memorandum directed readers to 42 C.F.R. § 422.100(m)(1), which provides that:

> When a state of disaster is declared . . . an MA organization . . . must, until [the end of the disaster], ensure access to benefits in the following manner:
>
> > (i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3).
> >
> > (ii) Waive, in full, requirements for gatekeeper referrals where applicable.
> >
> > (iii) Provide the same cost-sharing for the enrollee as if the service or benefit had been furnished at a plan-contracted facility.
> >
> > (iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3)."[29]

As of March 19, 2020, all states, territories and the District of Columbia have declared an emergency with respect to COVID-19.[30] Consequently, MA organizations across the nation, including those in Florida, must implement the special requirements outlined above through the stated end of the emergency.[31]

In the same memorandum, CMS, with the same goal of ensuring uninhibited access to healthcare services during the current COVID-19 crisis, informed Medicare plan sponsors of the various flexibilities available to them during – and in some instances, even absent – the COVID-19 crisis.[32]

Specifically, CMS recommended:

- Waiving or reducing cost-sharing for COVID-19 laboratory tests, telehealth benefits or other services used to address the outbreak – such waiver or reduction must apply uniformly to all similarly situated enrollees;
- Providing enrollees access to Part B services via telehealth in any location including beneficiaries' homes;
- Waiving prior authorization requirements for tests or services related to COVID-19;
- Relaxing "refill-too-soon" edits;
- Providing maximum extended day supply to enrollees;
- Reimbursing enrollees for prescriptions obtained from out-of-network pharmacies when enrollees cannot reasonably obtain Part D drugs from network pharmacies; and
- Allowing home or mail delivery of Part D drugs when enrollees are unable or prohibited from going to retail pharmacies.[33]

II. Florida OIR Guidance to Health Insurers

On March 6, 2020, the OIR issued an Informational Memorandum (the "Memorandum") to health insurers authorized to do business in Florida.[34] In the Memorandum, the OIR recommended that insurers:

- **Thwart misinformation by communicating accurate information concerning COVID-19**. Insurers should use every mode available to share information with policyholders and other industry players concerning COVID-19, including directing the public to the DOH website, www.FloridaHealth.gov/COVID-19. While there are many options for disseminating information to consumers including emails, phone calls and text messages, counsel should ensure that their clients comply with applicable federal and state law including, but not limited to, the Telephone Consumer Protection Act and the Florida Telemarketing Act found in Chapter 501 of the Florida Statutes when using such methods. At a minimum, health plans should make current and critical COVID-19 information available on their websites.

- **Eliminate barriers for testing and treatment of COVID-19.** OIR suggests that insurers consider reducing cost-sharing requirements related to COVID-19 testing and treatment. This would include reducing or waiving copays, coinsurances and deductibles related to COVID-19 testing. Insurers are also reminded that emergency services must be covered at the in-network level.[35]

- **Respond quickly to member inquiries.** OIR directs insurers to dedicate resources to quickly respond to consumer inquiries about available benefits, among other things. While not discussed in the Memorandum, Counsel and their clients may even consider providing expedited formulary exceptions for members suffering from life-threatening health conditions.

III. Business Continuity Plans and Additional Considerations

While addressing COVID-19, counsel and their health plan clients must be sure to review and update the insurer's Business Continuity Plan ("BCP").[36] In fact, the OIR is requiring that plans "provide a framework for the continuation of . . . key insurance functions such as policy issuance, premium collection, claims adjustment . . . and policyholder service" in their BCP, and that plans notify the OIR within the same day of activating the BCP.[37]

In short, while the steps for tackling COVID-19 vary with respect to health plans, the critical components are communication (including with policyholders), flexibility and preparedness.

Submitted by: **Tadena Simpson, Esq., Senior Counsel, *Envision Rx Options***

COVID-19:
REGULATORY UPDATES
Telehealth

Congress's COVID-19 Funding Legislation Expands Access to Telehealth Services for Medicare Beneficiaries

On March 6, 2020, President Donald Trump signed into law a $8.3 billion emergency coronavirus disease ("COVID-19") response funding package. In addition to providing funding for the development of treatments and public health funding for prevention, preparedness, and response, the bill authorizes the U.S. Secretary of Health and Human Services, Alex Azar (the "Secretary") to waive Medicare restrictions on the provision of services via telehealth during this public health emergency.[38]

On March 13, 2020, the Secretary issued a waiver for "requirements that physicians or other health care professionals hold licenses in the state in which they provide services if they have an equivalent license from another state." Greater utilization of telehealth during the COVID-19 outbreak will reduce providers' and patients' exposure to the virus in healthcare facilities. Telehealth is especially useful for mild cases of illness that can be managed at the patient's home, thereby decreasing the volume of individuals seeking care in facilities. To further facilitate the increased utilization of telehealth, the Centers for Disease Control and Prevention's interim guidance for healthcare facilities notes that healthcare providers can communicate with patients by telephone if formal telehealth systems are not available.[39] This allows providers to have greater flexibility when telehealth technology providers lack the bandwidth to accommodate this increase in telehealth utilization or are otherwise unavailable.

On March 17, 2020, President Trump and Seema Verma, CMS Administrator, announced that they are relaxing requirements imposed by the Health Insurance Portability and Accountability Act ("HIPAA") by permitting providers to use their mobile devices (FaceTime and Skype)—which normally may not fully comply with HIPAA requirements—to see patients. The Department of Health and Human Services, Office for Civil Rights ("OCR") also issued a Notification of Enforcement Discretion, in which it indicated that it "will not impose penalties for noncompliance with the regulatory requirements . . . in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency."[40]

Additionally, that same day, CMS issued a temporary telehealth waiver to allow for greater Medicare telehealth coverage, which will enable beneficiaries to receive a wider range of services from their doctor without traveling to a healthcare facility.[41] Clinicians can bill immediately for dates of services retroactive to March 6, 2020. Telehealth services are paid under the Physician Fee Schedule at the same amount as in-person services. Medicare coinsurance and deductive still apply for these services. In its announcement, CMS stated that Medicaid already provides a great deal of flexibility to states that wish to use telehealth services in their programs. No federal approval is needed for state Medicaid programs to reimburse providers for telehealth services in the same manner or at the same rate that states pay for face-to-face visits.

Regarding Medicaid reimbursement policies for telehealth, the policies vary from state-to-state. State policy changes in response to COVID-19 are still under development as of the writing of this article.

Similarly, private insurers' coverage of telehealth varies by payer and plan. Certain private insurers have announced plans to offer $0 copayments for telehealth visits and to expand access to telehealth for enrollees. On March 17, 2020, the Office of Inspector General ("OIG") released a policy statement to notify providers that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services furnished during the COVID-19 public health emergency declaration period.[42]

In response to the COVID-19 outbreak, some states have encouraged providers and health plans to increase utilization of telehealth.

Florida

Florida's laws already offered a level of protection for patients in need of emergency services. In accordance with Sections 627.64194, 627.662, and 641.513, Florida Statutes, and Section 2719A of the Public Health Service Act, insurers must cover emergency services for an emergency medical condition at the in-network level regardless of which provider performs the services. Additionally, when consumers receive emergency services from a health care provider that does not participate in the issuer's provider network, Florida law directs providers to ensure that consumers incur no greater out-of-pocket costs for the emergency services as they would have incurred with a participating provider.

On March 6, 2020, Florida's Office of Insurance Regulation (OIR) issued Informational Memorandum OIR-20-01M, which is aimed at removing actual or perceived barriers to testing for COVID-19.[43] The Memorandum advises that consumers could be reluctant to seek testing or treatment due to other anticipated costs, and directs commercial payors to consider all practicable options to reduce the barriers of cost-sharing for testing and treatment of COVID-19 during this public health emergency.

Florida was the first state to submit a waiver request to CMS to enable the state to, among other things, waive prior authorization requirements and streamline provider enrollment processes to ensure access to care for beneficiaries.[44] To date, Florida has made no COVID-19-related updates specific to telehealth coverage by Medicaid Managed Care.

Texas

On March 11, 2020, the Texas Department of Insurance issued a bulletin that strongly encourages insurers to consider waiving consumer cost-sharing to facilitate the expanded use of telehealth. To date, Texas has made no COVID-19-related updates specific to telehealth coverage by Medicaid Managed Care.[45]

While we await details on the waiver of geographic restrictions on telehealth services covered by Medicare, it is important to note that most states' laws require providers to be licensed in the state in which they are providing services. Acknowledging this requirement as a barrier to providing services for COVID-19, the Federation of State Medical Boards issued a press release to remind

state medical boards and health departments of its Physician Data Center resource,[46] which enables states to instantly verify licensure and disciplinary history for physicians and physician assistants nationwide. Use of this tool will expedite the practice of medicine across state lines, but the fastest option for cross-state practice would be for states to temporarily waive their license requirements for the duration of the public health emergency. Many states' laws provide for an exception to the in-state licensing requirement for physicians and other providers in emergency situations, although oftentimes "emergency" is not defined. However, as of March 16, 2020, at least eight (8) states have expressly waived certain provider licensing requirements or delegated such authority to the applicable regulatory agencies (Arizona, California, Florida, Louisiana, Mississippi, North Carolina, Tennessee, and Washington).

Finally, the Drug Enforcement Administration has waived the requirement that providers conduct an in-person evaluation of a patient prior to issuing prescriptions for controlled substances to patients, provided the following requirements are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;

- The telehealth communication is conducted using an audio-visual, real-time, two-way interactive communication system; and

- The practitioner is acting in accordance with applicable Federal and State law.[47]

This requirement will be waived for as long as the Secretary's designation of a public health emergency remains in effect.

Submitted by: **Audrey Davis, Esq., Elizabeth Scarola, Esq., & Kathleen Premo, Esq., *Epstein Becker & Green, P.C.***

COVID-19:
REGULATORY UPDATES
Telehealth

Telehealth for Behavioral Health and Addiction Treatment Providers Amid COVID-19

The COVID-19 pandemic has led many behavioral health and addiction treatment providers to consider offering telehealth services to patients to ensure that treatment services remain uninterrupted during this public health emergency. Due to the CDC guidelines on social distancing,[48] as well as state- and local government-issued bans or guidelines on gatherings of multiple people, many patients are not able to present for treatment services in person. Further, the Substance Abuse and Mental Health Services Administration ("SAMHSA") is advising that outpatient treatment options be used to the greatest extent possible to limit the spread of COVID-19.[49] Accordingly, SAMHSA is recommending the use of telehealth services to provide evaluation and treatment of patients.[50]

In response to COVID-19, the federal government has lifted several restrictions to enable providers greater flexibility with respect to telehealth services. Specifically, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") has issued a Notification of Enforcement Discretion (the "Notification"), under which it will temporarily lift penalties for violations of the HIPAA Privacy, Security, and Breach Notification Rules that occur in the good faith provision of telehealth services.[51] The Notification does not, however, apply to the waiver of penalties related to violations of the regulations that protect the confidentiality of substance use disorder ("SUD") patient records under 42 C.F.R. Part 2. SAMHSA's current guidance provides that the prohibitions on use and disclosure of patient information under 42 C.F.R. Part 2 may not apply, but only if the provider makes its own determination that the regulation's bona fide medical emergency exception applies.[52] Additionally, note that the CARES Act permanently revised these regulations regarding the use and disclosure of SUD records.[53]

For new patients treated with buprenorphine, a medication used to treat opioid use disorder, SAMHSA has exempted Opioid Treatment Programs ("OTPs") from the requirement to perform an in-person physical evaluation as normally would be required under the regulations[54] if a qualified professional determines that of the patient can be accomplished via telehealth.[55]

In Florida, the Governor has taken a broader approach, issuing Executive Orders "for the purpose of preparing for, responding to, and mitigating any effect of COVID-19, to expand the use of telehealth services.[56] However, at this time, there is no specific guidance in Florida regarding the use of telehealth for behavioral health or addition treatment providers. Providers should continue to monitor all federal and state guidance regarding he expansion of the use of telehealth as COVID-19 evolves.

With respect to reimbursement, many behavioral health and addiction treatment providers in Florida do not accept payment from the federally funded programs. Florida currently has no payment parity for services provided via telehealth. To address this disparity, Florida Medical Association President Ronald F. Giffler wrote a letter to Florida's Insurance Commissioner David

Altmaier and Governor Ron DeSantis requesting that the state require insurance companies to reimburse providers the same rates for providing telehealth services as in-person healthcare.[57]

Submitted by: **Sam Winikoff, Esq., *Beighley, Myrick, Udell & Lynne, P.A.***

COVID-19:
GENERAL RESOURCES

Below is a list of resources compiled by an HLS Updates contributor, which may be helpful to the HLS readers. Each resource is divided by applicable topic.

Agency Resources:

- **Centers for Disease Control and Prevention ("CDC"), Coronavirus**
  - Website: https://www.cdc.gov/coronavirus/2019-ncov/index.html

- **Centers for Medicare & Medicaid Services ("CMS"), Coronavirus Response**
  - Website: https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page

- **Equal Employment Opportunity Commission ("EEOC"), Coronavirus Information**
  - Website: https://www.eeoc.gov/coronavirus/

- **Health and Human Services, Office for Civil Rights: HIPAA, Civil Rights and COVID-19**
  - Website: https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html

Florida-Specific Resources on COVID-19:

- **Chapter 381, Florida Statutes, governing Public Health**
  - Website: http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&URL=0300-0399/0381/Sections/0381.00315.html

- **Florida Bar: COVID-19 Information and Resources**
  - Website: https://www.floridabar.org/news/releases/covid19

- **Florida Department of Health: COVID-19 Information**
  - Updated several times a day; contains current status/statistics in Florida
  - Website: https://floridahealthcovid19.gov/

- **Florida Department of Health: COVID-19 Resource Tool Kit**
  - Contains handouts to provide to clients and guidance regarding assisted living facilities, vulnerable populations, travel issues, etc.
  - Website: https://floridahealthcovid19.gov/resources/#toolkitJump

- **Florida Governor's Executive Orders and the State Surgeon General's Emergency Orders**
    - Website: http://www.flhealthsource.gov/covid19

General Resources, including Legal and Policy Resources

- **Association of State and Territorial Health Officials ("ASTHO")**
    - Recommended interventions documents, issues briefs, public health crisis communications, ventilator allocation issues, preparing for and responding to hospital and ICU surge, etc.
    - Website: https://www.astho.org/COVID-19/ASTHO-Resources/

- **Change Lab Solutions**
    - Compilation of resources, including links to Johns Hopkins Resource Center, American Public Health Association, WHO, CDC, Network for Public Health Law, ACLU pandemic preparedness materials, National Conference of State Legislatures, etc.
    - Website: https://www.changelabsolutions.org/blog/covid-19-resources

- **Health Affairs Journal**
    - A compilation of COVID-19-related articles, including expert analyses and policy proposals.
    - Website: https://www.healthaffairs.org/covid-19-coronavirus-disease

- **Johns Hopkins Bloomberg School of Public Health, Center for Health Security, Clinicians' Biosecurity News**
    - Article by Diane Meyer, RN, MPH and Elena Martin, MPH, titled "How to Reduce COVID-19 Spread in Long-Term Care Facilities: Challenges and Recommendations," published March 23, 2020.
    - Website: http://www.centerforhealthsecurity.org/cbn/2020/cbnreport-03232020.html

- **Keiser Family Foundation – Coronavirus Policy Watch**
    - Policy analysis, polling and updates on COVID-19
    - Website: https://www.kff.org/coronavirus-policy-watch

- **Keiser Family Foundation – Medicaid Emergency Authority Tracker: Approved State Actions to Address COVID-19**
    - Aggregates information by state on approved Medicaid emergency authorities to address COVID-19. Includes details on Section 1135 waiver and 1915(c) Waiver Appendix K strategies.
    - Website: https://www.kff.org/medicaid/issue-brief/medicaid-emergency-authority-tracker-approved-state-actions-to-address-covid-19

- **Keiser Family Foundation – State Data and Policy Actions to Address COVID-19**
  - Shows cases and deaths by state, and state actions to mitigate the spread of COVID-19
  - Website: https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/

- **National Hospice and Palliative Care Organization**
  - Website: https://www.nhpco.org/coronavirus

- **The Hastings Center**
  - Article by Lawrence O. Gostin, Eric. A Friedman, and Sarah A. Wetter, titled "Responding to COVID-19: How to Navigate a Public Health Emergency Legally and Ethically," published March 2020.
  - Website: https://www.thehastingscenter.org/responding-to-covid-19-how-to-navigate-a-public-health-emergency-legally-and-ethically/?blm_aid=20168

- **UCLA School of Law: Legal Responses to Coronavirus (COVID-19)**
  - Compilation of primary sources and summaries of states that have quarantine statutes and paid sick leave.
  - Website: https://libguides.law.ucla.edu/coronavirus

- **World Health Organization, COVID-19 Pandemic**
  - Website: https://www.who.int/

Legal and Policy Resources Regarding People with Disabilities and Mental Health Issues

- **COVID-19 Disability Community Preparedness Resources**
  - Website: https://docs.google.com/document/d/18tfi-0I8rpdJJ9Ubci45HYsy8sdutDpZv_eO-pdZDFc/edit#heading=h.kk1966kbedef

- **Disability Rights Education & Defense Fund**
  - Discusses preventing discrimination in the treatment of COVID-19 patients
  - Website: https://dredf.org/the-illegality-of-medical-rationing-on-the-basis-of-disability/

- **Employers' Consideration of the ADA and Other Disability Laws When Confronted with a Pandemic**
  - Q&A based on EEOC Guidance
  - Website: https://www.natlawreview.com/article/employers-must-consider-ada-and-other-disability-laws-when-confronted-pandemic

- **Mental Health Toolkit for Coronavirus Anxiety**
  - Website: https://www.virusanxiety.com/

Telemedicine

- **Medicare Telemedicine Health Care Provider Fact Sheet (Expansion of 1135 Waivers)**
  - Website: https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

- **Notification of Enforcement Discretion by the Office for Civil Rights:**
  - Website: https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

Webinars on COVID-19 (Miscellaneous Topics)

- **Alliance for Health Policy**
  - Synthesizes the information in the headline to provide cohesive insight into the status of the response and remaining gaps in the system that must be addressed to limit the severity of the COVID-19 outbreak in the United States. Contains six (6), half-hour, archived webinars. No CLE credit, but provides excellent information with commentary by national experts.
  - Website: http://www.allhealthpolicy.org/covid-19-webinar-series/

- **Coronavirus Developments**
  - A series of at least eight (8), free webinars for Florida CLE credit regarding coronavirus and a variety of related topics.
  - Website: https://www.pli.edu/coronavirus

- **EEOC Webinar, "COVID-19: Ask the EEOC" (March 27, 2020)**
  - This webinar will supplement COVID-19 publications already issued by the EEOC.
  - Website: https://www.youtube.com/watch?utm_content=&utm_medium=email&utm_name=&utm_source=govdelivery&utm_term=&v=i8bHOtOFfJU

- **Network for Public Health Resources**
  - Contains archived webinars regarding legal and policy challenges faced by counties, cities, and other localities, as well as their departments of health and emergency management.
  - Website: https://www.networkforphl.org/resources/covid-19-real-time-legal-responses-local-governments-on-the-frontlines/?blm_aid=20168

Submitted by: **Barbara L. Kornblau, Esq., *Law Office of Barbara L. Kornblau and Coalition for Disability Health Equity***

GENERAL UPDATES:
LEGISLATIVE UPDATES

First District Court of Appeal Affirms the 2018 Trauma Law's Constitutionality

In the 2018 legislative session, the Florida Legislature passed a comprehensive bill, House Bill 1165 (the "Bill"), that completely restructured the State's trauma system. The Bill was ultimately signed by Governor Rick Scott and went into effect on March 21, 2018.[58] This Bill became known as the "2018 Trauma Law," and will be referenced as such herein.

The 2018 Trauma Law implemented several significant changes to the trauma system, including:

- Modified the way trauma centers are allocated across Florida;
- Redistributed the allocated trauma centers into 18 Trauma Service Areas instead of the previously established 19 Trauma Service Areas;
- Revised the trauma licensure application and review process;
- Created new requirements for protesting the Department of Health's (the "Department") decisions regarding whether a trauma application should be approved or whether need has been established;
- Created an advisory council, comprised of subject-matter experts and stakeholders, to help the Department develop a more inclusive trauma system.

Due to the extensive changes made to the trauma system in the 2018 Trauma Law, the Florida Legislature also included a section in the law that addressed the status of every single trauma program that was verified, provisionally approved, or in the application process at the time that the law was enacted. This was meant to prevent any confusion as to the status of the various trauma programs once the 2018 Trauma Law went into effect. This language was codified in Section 395.4025(16), Florida Statutes. Moreover, the Florida Legislature also included a non-severability clause, which stated that if the provisions identifying the legal status of the trauma programs were held to be invalid or inoperative for any reason, "the remaining provisions of this act shall be deemed to be void and of no effect, it being the legislative intent that this act as a whole would not have been adopted had any provision of the act not been included."[59]

As a result of the 2018 Trauma Law, Kendall Regional Medical Center ("Kendall Regional") became a verified Level I Trauma Program. The specific authority for this action is found in Section 395.4025(16)(c), Florida Statutes (2018). Prior to the enactment of the 2018 Trauma Law, Kendall Regional was operating as a provisionally approved Level I Trauma Program since its Level I trauma verification was in the process of being administratively challenged by Nicklaus Children's Hospital ("Nicklaus").

Due to the change in Kendall Regional's verification status, Nicklaus brought a declaratory action against the Department in the Leon County Circuit Court seeking to invalidate Section 395.4025(16)(c), Florida Statutes.[60] In its Complaint, Nicklaus alleged that Section 395.4025(16)(c), Florida Statutes, is unconstitutional because it is an improperly enacted special law, since it creates a closed class, which only Kendall Regional can be a part of. Nicklaus also alleged that Section 395.4025(16)(c), Florida Statute, is unconstitutional because it is a special law that grants a benefit to a private corporation. Kendall Regional and Jackson South Medical Center

("Jackson South") both intervened in this proceeding to support the Department's position. Jackson South had standing in this proceeding as its trauma program was verified as a Level II trauma program pursuant to the authority granted in Section 395.4025(16), Florida Statutes. Due to the non-severability clause in the 2018 Trauma Law, Jackson South's verification could be jeopardized if Section 395.4025(c), Florida Statutes, was found to be invalid.

As the circuit court proceeding went on, Kendall Regional filed a Motion for Summary Judgment, which the Department and Jackson South joined in on. In in its Motion, Kendall Regional argued that Section 395.4025(16)(c), Florida Statutes, was not a special law, since it is an integral part of a statute that applies uniformly to all trauma centers in the state and serves an important statewide interest. After a hearing on the Motion, Circuit Court Judge Charles Dodson entered an Order granting Kendall Regional's Motion for Summary Judgment, in which he stated, in part:

> Kendall is entitled to summary judgment because, as a matter of law, Section 395.4025(16)(c) is not a special law, but instead is one integral element of the 2018 Trauma Law. This legislative act is a comprehensive overhaul of the State's trauma system and clarifies the licensure status of every trauma center in the State. It bears no resemblance to the statutes which have been invalidated as special laws, which only provide special benefits to one or a limited number of entities and serve no statewide purpose.[61]

After the trial court entered the final judgment in this matter, Nicklaus appealed the trial court's decision to the First District Court of Appeal.

At the appellate level, the parties again argued the positions they had each taken at the trial level in this matter. The First District Court of Appeal held oral arguments in this case on February 19, 2020. Subsequently, on February 25, 2020, the First District Court of Appeals issued its Order affirming, per curiam, the trial court's decision finding the challenged portion of the 2018 Trauma Law to be a constitutional general law.[62]

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

GENERAL UPDATES:
LEGISLATIVE UPDATES

House Bill 1193 Proposes to Expand Practice of Dietetics and Nutrition Counseling Beyond Licensed Practitioners

Historical Florida Dietetics Practice Law and 2020 House Bill 1193

A 2020 Bill under consideration by the Florida House of Representatives, House Bill 1193 ("HB 1193"),[63] would allow anyone to sell nutrition counseling services and provide nutrition-related recommendations to consumers, as long as they do not represent themselves to be a registered or licensed dietitian.

Currently, the Florida Statutes governing dietetics and nutrition counseling provide that "[t]he Legislature finds that the practice of dietetics and nutrition or nutrition counseling by unskilled and incompetent practitioners presents a danger to the public health and safety."[64] As a result, the statutes state that "[n]o person may engage for remuneration in dietetics and nutrition practice or nutrition counseling or hold himself or herself out as a practitioner of dietetics and nutrition practice or nutrition counseling unless the person is licensed in accordance with the provisions of this part."[65] To be eligible for licensure as a dietician or nutritionist, the law currently requires that the individual:

> (a) Possesses a baccalaureate or postbaccalaureate degree with a major course of study in human nutrition, food and nutrition, dietetics, or food management, or an equivalent major course of study, from a school or program accredited, at the time of the applicant's graduation, by the appropriate accrediting agency recognized by the Commission on Recognition of Postsecondary Accreditation and the United States Department of Education; and
>
> (b) Has completed a preprofessional experience component of not less than 900 hours or has education or experience determined to be equivalent by the board; or
>
> 1. Has an academic degree, from a foreign country, that has been validated by an accrediting agency approved by the United States Department of Education as equivalent to the baccalaureate or postbaccalaureate degree conferred by a regionally accredited college or university in the United States;
>
> 2. Has completed a major course of study in human nutrition, food and nutrition, dietetics, or food management; and
>
> 3. Has completed a preprofessional experience component of not less than 900 hours or has education or experience determined to be equivalent by the board.[66]

HB 1193 would revise the current law by explicitly noting that the statutes should not be construed as prohibiting or restricting the practice, services, or activities of "[a] person who provides information, recommendations, or advice concerning nutrition, or who markets food, food

materials, or dietary supplements for remuneration, if that person does not represent himself or herself as a dietitian, licensed dietitian, registered dietitian, licensed nutritionist, nutrition counselor, or licensed nutrition counselor, or use any word, letter, symbol, or insignia indicating or implying that he or she is a dietitian, nutritionist, or nutrition counselor."[67]

Potential Effects and Current Status of HB 1193

In 2004, Crunch Fitness settled a lawsuit for over $4 million when a woman died, allegedly as a result of a personal trainer's recommendations to take a variety of over-the-counter nutritional and dietary supplements.[68] In 2013, an article was published on nutrition practices and knowledge of personal trainers in the *Journal of Community Medicine and Health Education (Sports Nutrition Knowledge and Practices of Personal Trainers).*[69] The article contained a survey of 129 personal trainers, which showed that more than 90% of personal trainers spent time on nutrition counseling with clients. Approximately 42.6% acknowledged that their fees included charges for nutrition counseling. As part of the survey, the personal trainers were asked eight (8) basic true-false nutrition knowledge questions and the results revealed an average nutrition knowledge score of 59.7%.

Forty-seven (47) states, including Florida, have enacted legislation regulating the practice of dietetics, in an effort to prevent potential harm resulting from the unregulated practice of dietetics and nutrition counseling. However, Florida has proposed to reverse course with HB 1193.

In January 2020, HB 1193 was supported by the Government Operations and Technology Appropriations Subcommittee and the Business and Professions Subcommittee. In February 2020, the HB 1193 received unanimous support by the Commerce Committee. The Committee Substitute is currently under review by the Commerce Committee.

Submitted by: **Jessica Weissman, PhD, RDN, LDN,** ***Program Director and University Department Chair at Keiser University, Melbourne, Bachelor of Science in Dietetics and Nutrition Program***

GENERAL UPDATES:
LEGISLATIVE UPDATES

Summary of 2020 Florida Legislative Session Initiatives

Florida's 2020 legislative session adjourned Sine Die (Latin for "without day") March 19, 2020. Session typically runs for 60 consecutive days. On even-numbered years, session is held January through March, and on odd-numbered years, session is held from March through May. The 60-day session began January 14, 2020, and was scheduled to end March 13, 2020. However, lawmakers extended session to ensure funds were allocated to account for economic impacts of COVID-19. Legislators unanimously adopted its 2021 $93.2 billion-dollar budget in less than two (2) hours. The budget earmarks $300 million dollars of Florida's reserves for COVID-19, in addition to $25.5 million dollars requested by Governor DeSantis and another $27.3 million in federal assistance. However, speculation is growing that legislators will be back in special session before July 1, 2020, to reexamine the budget. Florida's Chief Financial officer, Jimmy Patronis, has requested budget experts to begin to examine the economic impact in light of significant loss of tourism and sales tax revenue.

In the 2020 session, Speaker of the House, Jose Oliva, indicated that his legislative priorities included an initiative to drive down healthcare costs, promote free market and increase access. This included expanding the scope of practice for advanced practice nurse practitioners ("APRNs") and pharmacists. Effective July 1, 2020, APRNs may autonomously practice primary care. Further, pharmacists who enter into collaborative agreements may test and treat patients for flu and strep, as well as manage certain chronic care conditions. Another derivative of Oliva's free market and access to care initiative is the passage of automated pharmacy systems and the prescription drug donation repository program. Under automated pharmacy systems, community pharmacies can provide outpatient dispensing through the use of an automated machine, similar to a vending machine. The drug repository program allows Floridians to donate prescriptions so those who cannot afford them. We can expect rules to be promulgated in the near future that will outline the parameters of these initiatives.

Consumer protection was another priority of the 2020 session. Incoming Speaker of the House, Representative Chris Sprowls (R-Tarpon Springs), sponsored legislation to amend Florida's genetic testing laws. The law prohibits life and long-term care insurers from cancelling, limiting, or denying coverage or setting varying rates based on an applicant's genetic information, for example, using 23andme. However, this will allow the use of documented medical diagnoses and allows life and long-term care insurers to access an applicant's medical records as part of the underwriting process.

Another pro-consumer legislative initiative regulates the billing practices of air ambulances. Air ambulances provide emergency and non-emergency services to patients similar to ground ambulances. There has been a lot of discussion regarding patients being billed for charges in excess of what health insurers reimburse air ambulance providers. This balance billing practice is no longer permitted; however, it is unclear whether there will be preemption challenges (citing the Airline Deregulation Act of 1978) to the implementation of this law upon enforcement.

In addition to pro-consumer legislation, lawmakers focused on modernizing archaic statutes. For example, certain changes to licensure requirements for nurse registries and physical therapy practice, and revisions to statutes pertaining to the Department of Health overhaul and the Agency for Health Care Administration ("AHCA") all passed and are set to take effect by next year. The goal is to ease the regulatory burdens of the Department of Health and AHCA and modernize Florida's current laws to better reflect today's practice.

Submitted by: **Nicole M. Perez, J.D., Government & Legislative Relations Manager, *Florida Blue***

GENERAL UPDATES:
REGULATORY UPDATES

OIG Permits Pharmaceutical Company to Pay Patient Expenses

The Office of Inspector General ("OIG") issued an Advisory Opinion (No. 20-02) on January 21, 2020 that approved an arrangement in which a pharmaceutical manufacturer would provide travel, lodging, and other expenses to financially needy patients prescribed the manufacturer's medication.[70] The OIG noted that the arrangement could violate the federal Antikickback Statute and the beneficiary inducements prohibitions of the Civil Monetary Penalties Law ("CMPL"); however, under the circumstances of this arrangement, the OIG would not impose sanctions.

The specific arrangement evaluated in the OIG's Advisory Opinion involved a pharmaceutical company (the "Requestor") that manufactures an FDA-approved drug.[71] The drug is a personalized medication made from the patient's own cells and is a "one-time, potentially curative treatment." The drug has a black box warning for certain life-threatening or fatal reactions. The FDA requires the manufacturer to implement a risk evaluation and mitigation strategy ("REMS"), and only REMS-certified physicians can prescribe the drug. Further, facilities that meet certain criteria are eligible to become a center ("Center") to administer the drug. The FDA requires physicians to monitor patients several times during the first week of using the drug, which requires patients to remain close to a Center to mitigate any risk.

The Requestor stated that indigent or rural patients could be "disproportionately impacted by significant health risks or even death" if they are unable to travel to a Center after receiving the drug. To be eligible, patients must have a household income that does not exceed 600 percent of the federal poverty level, live more than two (2) hours or 100 miles from the closest Center and have no insurance for non-emergency medical travel. For these patients, the arrangement would provide for travel, modest lodging, meals and certain out-of-pocket expenses ($50.00 per person) during and after the administration of the drug.

The OIG's legal analysis focused on the Antikickback Statute, which makes it a crime to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program.[72] The OIG noted that the manufacturers could use the reimbursements to generate business and the Requestor could increase the drug's price to recoup the costs associated with the arrangement. The OIG noted that these concerns could result in increased costs to federal healthcare programs.

However, the OIG stated that it would not impose sanctions against the Requestor for this arrangement for the following reasons:

1. The majority of patients eligible to receive the drug are Medicare or Medicaid beneficiaries with an annual household income of $28,000.00. The OIG stated it would permit the arrangement because it would "increase access to care for financially needy patients and those living in rural areas."

2. The remuneration relates to expenses incurred by a patient to adhere to his/her physician's instructions to receive treatment at a qualified Center and to remain close to that Center, as required by the FDA-approved prescribing information.

3. The FDA requires that only physicians who accept responsibility for implementing safety protocols are eligible to participate, thus the number of physicians who can participate is limited. Further, the Requestor does not require physicians or Centers to prescribe their drug, and any facility that meets the Requestor's requirements can become a Center. Therefore, the OIG concluded that the arrangement would limit the likelihood that the Requestor would use the arrangement to reward physicians who prescribe or administer the drug.

4. The drug is a one-time, potentially curative treatment, thus, it does not raise the usual concerns present in other arrangements. Further, the Requestor does not advertise the arrangement, which would limit the chances it would be used as a marketing tool to drive patients to its drug.

5. The arrangement does not duplicate other available financial assistance, for example, the Requestor does not authorize payment for lodging if the patient is eligible to receive lodging at the Center.

The OIG also determined the arrangement would implicate the beneficiary inducements CMPL, which prohibits a person or entity from offering or providing any remuneration to a Medicare or Medicaid beneficiary that the offeror knowns, or should know, is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier. The OIG noted that the arrangement could influence a patient to select a physician or Center in the Requestor's network they might not otherwise select. However, the OIG determined that the arrangement satisfies the Promote Access to Care Exception to the CMP, which states that "remuneration poses a low risk of harm if it is (i) unlikely to interfere with, or skew, clinical decision making; (ii) unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) does not raise patient safety or quality-of-care concerns."

As with any Advisory Opinion, it is limited to the specific facts in this case.

Submitted by: **Amy Morse, Esq., *Morse & Morse, LLC***

[1] 45 C.F.R. §164.308(a)(5).
[2] *Id.* §§ 164.312(a)(2); 164.316.
[3] "SANS Security Awareness Work-from-Home Deployment Kit," SANS Security Awareness, *available at* https://www.sans.org/security-awareness-training/sans-security-awareness-work-home-deployment-kit.
[4] *See* 45 C.F.R. § 164.308(a)(3).
[5] 42 U.S.C. § 290dd-2; 42 C.F.R. Part 2 (both collectively referred to as "Part 2").
[6] This Update was originally prepared by the Author prior to the DOL's issuance of the temporary rule on April 2, 2020. As such, the HLS Editors have replaced the original submission with this updated version generously prepared by the Author.
[7] 85 FED. REG. 19326 (April 6, 2020).
[8] Families First Coronavirus Response Act, Pub. L. No. 116-127 (2020).
[9] *Id.*
[10] § 3105; § 5102.
[11] *Id.*
[12] § 5102.
[13] *Id.*
[14] § 5102(e)(1); § 5110(1).
[15] § 5110(2).
[16] § 5102(b)(2).
[17] § 5110(3)(b)(i).
[18] § 5110(3)(b)(ii).
[19] See § 110(a)(2)(A).
[20] *Id.*
[21] § 110(a)(1)(B).
[22] § 110(a)(1)(A).
[23] § 110(b)(2).
[24] § 110(b)(1).
[25] § 110(b)(2)(B)(i).
[26] *Id.*
[27] § 110(b)(2)(B)(ii).
[28] Centers for Medicare and Medicaid Services, "Information Related to Coronavirus Disease 2019 – COVID-19," *available at* https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf (Mar. 10, 2020).
[29] 42 C.F.R. § 422.100(m)(1).
[30] National Governors Association, *State Tracking* Chart, *available at* https://www.nga.org/wp-content/uploads/2020/03/COVID19StateTrackingChart.pdf and https://www.nga.org/coronavirus/ (last visited Mar.19, 2020).
[31] 42 C.F.R. § 422.100(m)(3).
[32] *See supra*, note 28 (stating that MA Organizations may waive prior authorization requirements that otherwise would apply to tests or services related to COVID-19 at any time, and also provides that "Part D sponsors may relax edits in the absence of declarations if they determine it is appropriate to ensure pharmacy access").
[33] *Id.*
[34] Florida OIR, Informational Memorandum OIR-20-01M, *available at* https://www.floir.com/siteDocuments/OIR-20-01M.pdf (March 6, 2020).
[35] FLA. STAT. §§ 627.64194, 627.662, and 641.513.
[36] MA plans and Part D sponsors are required to have BCPs pursuant to 42 C.F.R. §§ 422.504(o) and 423.505(p), respectively.
[37] Florida OIR, Informational Memorandum OIR-20-03M, https://www.floir.com/siteDocuments/OIR-20-03M.pdf (March 16, 2020).
[38] "Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus," HHS.gov, Immediate Press Release (Jan. 31, 2020), *available at* https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html.
[39] "Interim Guidance for Healthcare Facilities: Preparing for Community Transmission of COVID-19 in the United States," CDC: Coronavirus Disease 2019 (COVID-19), *available at* https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-hcf.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhealthcare-facilities%2Fguidance-hcf.html.

[40] "Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency," HHS.gov, Health Information Privacy, *available at* https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.
[41] "Medicare Telemedicine Health Care Provider Fact Sheet," CDC.gov, Newsroom (Mar. 17, 2020), *available at* https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet.
[42] "OIG Police Statement Regarding Physicians and Other Practitioners that Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus Outbreak," Office of Inspector General (Mar. 17, 2020), *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf.
[43] "Insurance Coverage for Coronavirus (COVID-19)," Florida Office of Insurance Regulation, Informational Memorandum OIR-20-01M (Mar. 6, 2020), *available at* https://www.floir.com/siteDocuments/OIR-20-01M.pdf.
[44] "Section 1135 Flexibility Requested in March 13, 2020 Communication," Correspondence to Ann Dalton, AHC Administrator, Bureau of Medicaid Policy (Mar. 16, 2020), *available at* https://www.medicaid.gov/state-resource-center/downloads/fl-section-1135-appvl.pdf.
[45] "COVID-19 testing and preparation," Texas Department of Insurance, Commissioner's Bulletin # B-0005-20 (Mar. 11, 2020), *available at* https://www.tdi.texas.gov/bulletins/2020/B-0005-20.html.
[46] "FSMB Statement on Supporting States in Verifying Licenses for Physicians Responding to COVID-19 Virus," Federation of State Medical Boards, *available at* http://www.fsmb.org/advocacy/news-releases/fsmb-statement-on-supporting-states-in-verifying-licenses-for-physicians-responding-to-covid-19-virus/.
[47] "COVID-19 Information Page," Drug Enforcement Administration, Diversion Control Division, *available at* https://www.deadiversion.usdoj.gov/coronavirus.html.
[48] "Social Distancing, Quarantine and Isolation, CDC: Coronavirus Disease 2019 (COVID-19), *available at* https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html.
[49] "Considerations for the Care and Treatment of Mental and Substance Use Disorders in the COVID-19 Epidemic," SAMHSA, *available at* https://www.samhsa.gov/sites/default/files/considerations-care-treatment-mental-substance-use-disorders-covid19.pdf.
[50] "COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance," SAMHSA, *available at* https://www.samhsa.gov/sites/default/files/covid-19-42-cfr-part-2-guidance-03192020.pdf.
[51] "Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency," HHS.gov, Health Information Privacy, *available at* https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.
[52] *See supra*, note 50.
[53] See article in this edition of the HLS Updates for more information, titled "CARES Act Modernizes Confidentiality & Use of Substance Use Disorder Patient Records."
[54] *See* 42 C.F.R. § 8.12(f)(2).
[55] "FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency," SAMHSA, *available at* https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf.
[56] Emergency Order DOH No. 20-002, *In Re: Suspension of Statutes, Rules and Orders, Made Necessary by COVID-19*, State of Florida, Department of Health (Mar. 16, 2020), *available at* http://www.flhealthsource.gov/pdf/emergencyorder-20-002.pdf.
[57] "Florida's largest medical association seeks telehealth payment mandates as coronavirus spreads," News4Jax, *available at* https://www.news4jax.com/news/florida/2020/03/20/floridas-largest-medical-association-seeks-telehealth-payment-mandates-as-coronavirus-spreads/.
[58] *See* Ch. 2018-66, Laws of Florida.
[59] *Id.* § 14.
[60] *Variety Children's v. Dep't of Health*, No. 2018 CA 001072 (Fla. 2d Cir. Ct. May 10, 2018).
[61] *Order Granting Kendall Healthcare Group, LTD's Motion for Summary Judgment, Variety Children's Hospital v. Dep't of Health*, No. 2018 CA 001072 (Fla. 2d Cir. Ct. April 29, 2019).
[62] *Variety Children's Hospital v. Dep't of Health*, No. 1D19-1842, 2020 WL 917372 (Fla. 1st DCA Feb. 25, 2020).
[63] HB 1193 can be accessed at: https://www.flsenate.gov/Session/Bill/2020/1193/BillText/c1/PDF.
[64] FLA. STAT. § 468.502.
[65] *Id.* § 468.504.
[66] *Id.* § 468.509(2).

[67] This would be located at Section 468.505(1)(n), Florida Statutes.
[68] *Capati v. Crunch Fitness Int'l, Inc.*, 295 A.D.2d 181 (N.Y. App. Div. 2002).
[69] In an effort to be transparent, please note that the author of this article published this survey in the *Journal of Community Medicine and Health Education*.
[70] OIG Advisory Opinion No. 20-02 (Jan. 15, 2020), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2020/AdvOpn20-02.pdf.
[71] OIG does not name or identify the drug or manufacturer.
[72] 42 U.S.C. § 1302a-7b(b).