August 2020

Dear Health Law Section Members:

The Health Law Section ("HLS") website has been updated with June through July 2020 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 the HLS. HLS thanks the following volunteers who have generously donated their time to prepare these summaries for our members:

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TABLE OF CONTENTS

LEGISLATIVE UPDATES

Florida Legislature Repeals the Department of Health's Authority to Discipline Healthcare Providers for Failing to Repay Student Loans

Over a year ago, in the February 2019 Health Law Section updates, we reported on the Department of Health's ("DOH") power to suspend a healthcare practitioner's occupational license for defaulting on student loans. This authority arose from Section 456.072(1)(k), Florida Statutes, and Section 456.074(4), Florida Statutes, which specifically required that DOH suspend a practitioner's occupational license if he or she failed to repay a student loan that was issued or guaranteed by the state or federal government. Section 456.072(1)(k), Florida Statutes, further instructed that the healthcare practitioner's occupation license should remain suspended "until new payment terms are agreed upon . . . , followed by probation for the duration of the student loan[.]" Moreover, a healthcare practitioner that was found guilty of violating Section 456.072(1)(k), Florida Statutes, also incurred a fine that was "equal to 10 percent of the defaulted loan amount." These statutes were not simply empty threats, but instead were often utilized by DOH to enforce loan repayment.[1] Notably, "[d]uring the 2017-2018 Fiscal Year, DOH handled 247 cases against healthcare practitioners for defaulting on student loans, and during the 2018-2019 Fiscal Year, DOH handled 722 cases."[2]

While these types of disciplinary laws were originally supported by the federal government, in recent years "there have been attempts at the national level to prohibit state disciplinary laws for defaulting on government-backed student loans."[3] As a result, in the 2020 Legislative Session, the Florida Legislature enacted two bills that withdrew DOH's authority to discipline healthcare practitioners for defaulting on student loans. House Bill 115 modifies Section 456.072(1)(k), Florida Statutes, as follows:

> Failing to perform any statutory or legal obligation placed upon a licensee. For purposes of this section, failing to repay a student loan issued or guaranteed by the state or the Federal Government in accordance with the terms of the loan <u>is not</u> ~~or failing to comply with service scholarship obligations shall be~~ considered a failure to perform a statutory or legal obligation~~, and the minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount~~. Fines collected shall be deposited into the Medical Quality Assurance Trust Fund.[4]

Section 456.074(4), Florida Statutes,[5] was repealed in its entirety by both House Bill 115 and House Bill 713.[6] Accordingly, pursuant to the Legislature's actions, the DOH no longer has the authority to discipline a healthcare practitioner, in any manner, for defaulting on a student loan.

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

LEGISLATIVE UPDATES

Changes to the Guardianship Law Cracks Down on the Use of Do Not Resuscitate Orders

On June 18, 2020, Governor DeSantis signed Senate Bill 994 into law, which became effective July 1, 2020, prohibiting guardians from signing Do Not Resuscitate ("DNR") orders without court approval, among other changes to the guardianship law, including the appointment of a guardian, mandated guardianship reports, conflicts of interest, and a guardian's ability to sign DNRs. This summary primarily focuses on the amendments to the law with respect to DNR orders and the protections provided therein.

A plenary or limited guardian now will be required to obtain court approval before signing a DNR on behalf of a ward. In emergency circumstances, guardians must follow the procedures set forth in Florida Probate Rule 5.900 regarding expedited judicial intervention concerning medical treatment. The court then must hold a preliminary hearing within 72 hours of the filing of the petition and rule on the petition immediately after the preliminary hearing or conduct an evidentiary hearing no later than four (4) days after the preliminary hearing and rule on the petition immediately after the evidentiary hearing.[7]

The new law expands the requirements for guardianship plans. The plan must specify information relating to any preexisting DNR orders or preexisting advance directives.[8] Additionally, the content plan should include the date an order or directive was signed, whether the court suspended the order or directive, and a description of the steps taken to identify and locate the order or directive.[9] This information must be included in the initial guardianship plan and every annual guardianship plan thereafter.[10]

With Florida's growing vulnerable adult population heavily dependent on guardianship services, this amendment to the law is significant. It provides more oversight from the courts and more protection for Florida's vulnerable adult community.

Submitted by: **Ariel Cavazos, Esq., & Emily Greentree, University of Florida Levin College of Law, Summer Associate*, Nelson Mullins Broad and Cassel***

LEGISLATIVE UPDATES

New Florida Law Requires Written Consent for Pelvic Examinations

With the passage of Senate Bill 698 by the Florida Legislature, effective July 1, 2020, all Florida health care providers, and providers in training, are now required to obtain written consent from their patients (or their legal representatives) before performing a pelvic examination. The only exceptions to this requirement are when a pelvic examination is performed pursuant to a court order or in cases of emergency. The original intent of the legislation was to ensure that a pelvic examination could not be performed on an anesthetized female patient without her consent. However, the Florida Legislature amended Senate Bill 698 to contain broad-sweeping language that exceeds the original intent of the legislation, resulting in significant requirements on any Florida health care practitioner providing pelvic examinations.

In relevant part, Senate Bill 698 defines a "pelvic examination" as "a series of tasks that comprise an examination of the vagina, cervix, uterus, fallopian tubes, ovaries, rectum, or external pelvic tissue or organs using any combination of modalities, which may include, but need not be limited to, the health care provider's gloved hand or instrumentation."

As an initial matter, it is unclear whether Senate Bill 698 applies only to female patients, or includes pelvic examinations performed on male patients. The final version of Senate Bill 698 removed reference to the female internal reproductive system and added the term "rectum." The Florida Department of Health ("DOH") has indicated that the provisions of the legislation apply to both female and male patients because there is no gender referenced in the definition of pelvic examination in the final version of the bill.

It also remains unclear how often a practitioner must obtain written consent. Senate Bill 698 provides that a pelvic examination may not be performed without the written consent of the patient "executed specific to, and expressly identifying the pelvic examination." Based on this language, DOH has advised that written consent appears to be required for each pelvic examination and written consent may not cover future examinations. Other uncertainties include whether inserting catheters in a patient would fall under the legislation's definition of a pelvic examination and how Senate Bill 698 may impact certain specialists. For example, Senate Bill 698 is silent on whether written patient consent is required when pediatricians and/or radiologists perform external pelvic tissue exams or imaging.

To address the uncertainties created by the passage of Senate Bill 698, petitions for declaratory statements were filed with the Florida Board of Medicine and Florida Board of Nursing seeking interpretations of Senate Bill 698. The petitions were filed by some of Florida's largest medical groups, including the Florida Medical Association, Florida Nurses Association, the Florida Academy of Family Physicians, the Florida Chapter of the American Academy of Pediatrics, the Florida Chapter of the American College of Physicians and the Florida Society of Dermatologists and Dermatological Surgeons.

The Florida Medical Association also requested a declaratory statement from the Florida Board of Medicine seeking clarification regarding the following:

- That the law does not apply to males;
- That the law does not apply to surgical procedures involving organs such as the vulva, vagina, ovaries, uterus and rectum;
- That the law does not apply to insertion of catheters or cleaning of the pelvic area during a diaper change;
- That the law does not apply to visual exams of the pelvic area; and
- That written consent for an initial pelvic exam is sufficient for any additional pelvic exams needed during treatment.

The Florida Board of Medicine has a meeting scheduled for August 7, 2020 at which these issues are to be considered.

Finally, no specific consent form language is mandated by Senate Bill 698. The Florida Medical Association has developed a sample written consent form that can be used as a template.

The disconnect between the original intent of Senate Bill 698 (ensuring a pelvic examination could not be performed on an anesthetized female patient without her consent) and the wide scope and operative language found in the final version of the legislation is clearly creating issues. Guidance from relevant licensure boards will be necessary to determine the true breadth of Senate Bill 698. Accordingly, Florida health care practitioners should take a conservative approach until such guidance is published and obtain written consent from their patients (or their legal representatives) before performing any pelvic examination.

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

LEGISLATIVE UPDATES

House Bill 6971 Proposes to Expand Medical Nutrition Therapy Services of the Medicare Program

A 2020 bill under consideration by the House of Representatives, the "Medical Nutrition Therapy Act of 2020" ("HR 6971"), would amend title XVIII of the Social Security Act to expand the availability of medical nutrition therapy services under the Medicare program.[11] Currently, Medicare beneficiaries can receive medical nutrition therapy if diagnosed with diabetes or renal disease.[12] HR 6971 would allow Medicare beneficiaries with the following conditions to receive medical nutrition therapy services:

> (A) Diabetes and prediabetes.
> (B) A renal disease.
> (C) Obesity (as defined for purposes of subsection (yy)(2)(C) or as otherwise defined by the Secretary).
> (D) Hypertension.
> (E) Dyslipidemia.
> (F) Malnutrition.
> (G) Eating disorders.
> (H) Cancer.
> (I) Celiac disease.
> (J) HIV.
> (K) AIDS.
> (L) Any other disease or condition—
>
> > (i) specified by the Secretary relating to unintentional weight loss;
> >
> > (ii) for which the Secretary determines the services described in paragraph (1) to be medically necessary and appropriate for the prevention, management, or treatment of such disease or condition, consistent with any applicable recommendations of the United States Preventive Services Task Force; or
> >
> > (iii) for which the Secretary determines the services described in paragraph (1) are medically necessary, consistent with either protocols established by registered dietitians or nutrition professional organizations or with accepted clinical guidelines identified by the Secretary.

HR 6971 would revise the Social Security Act by noting that persons with several of the risk factors for the leading causes of death are eligible to receive medical nutrition therapy services for such conditions.[13]

Potential Effects and Current Status of HR 6971

Currently, beneficiaries of the Medicare program are eligible to receive medical nutrition therapy services if diagnosed with diabetes or renal disease. However, this eligibility criteria excludes individuals with heart disease and cancer, the two leading causes of death in the U.S. HR 6971 proposes to expand medical nutrition therapy services to those with cancer and with known risk factors of heart disease: hypertension, dyslipidemia, and obesity. Furthermore, chronic conditions such as obesity and cancer cost the U.S. health care system over $140 billion a year.[14] Obesity and cancer may be preventable via medical nutrition therapy.

On May 23, 2020, HR 6971 was introduced in the Senate. The amendments made in HR 6971 would apply to services furnished on or after January 1, 2021.

Submitted by: **Jessica Weissman, PhD, RDN, LDN, Program Director and University Department Chair*, Keiser University***

LEGISLATIVE UPDATES

Florida House Bill 607
Approves Greater Autonomy for Nurse Practitioners

On March 11, 2020, Governor DeSantis signed House Bill 607 into law, authorizing advanced practice registered nurses ("APRN") to start their own autonomous practices and practice primary care and midwifery without a supervisory protocol or supervision by a physician. The goal of this bill was to allow Floridians greater access to health care professionals, especially in rural areas where physicians are in short supply. Although House Bill 607 became effective July 1, 2020, APRNs may not practice autonomously until the Board of Nursing ("Board") adopts rules regarding this practice.

To practice autonomously, an APRN will have to register with the Board. The APRN must hold an active and unencumbered Florida license, and: (1) complete at least 3,000 clinical practice or instructional hours supervised by an actively licensed physician within the five-year period immediately before registration, (2) not been subject to any disciplinary action during the five years immediately before the registration, (3) complete three graduate-level semester hours in pharmacology and three graduate-level semester hours in differential diagnosis within the five-year period before registration, and (4) complete any other requirements adopted by the Board. The registration must be renewed biennially. The APRN must complete a minimum of ten hours of continuing education approved by the Board for each biennial renewal.

An APRN registered for autonomous practice may engage in primary care practice, including family medicine, general pediatrics, and general internal medicine. A registered APRN may: (1) admit, discharge, or manage the care of a patient requiring the services of a health care facility; (2) provide a signature, certification, stamp, verification, affidavit, or other endorsement that is otherwise required by law to be provided by a physician; (3) certify causes of death and sign, correct, and file death certificates; (4) execute a certificate to subject a person to involuntary examination under the Baker Act; (5) perform certain physical examinations currently reserved to physicians and physician assistants by Florida law, such as examinations of pilots, law enforcement officers, and suspected child abuse victims; and (6) examine and report on a ward's medical and mental health conditions in the annual guardianship plan submitted to a court. A certified nurse midwife may only perform midwifery services if the certified nurse midwife has a written patient transfer agreement with a hospital and a written referral agreement with a Florida-licensed physician. An APRN may not perform any surgical procedures except subcutaneous surgical procedures.

The Board, at its June 5, 2020 meeting, voted to promulgate rules regarding autonomous practice. The Board proposed defining primary care practice to include "health promotion, disease prevention, health maintenance, counselling, patient education, and diagnosis and treatment of acute and chronic illnesses in a variety of healthcare settings" through the rulemaking process.

An APRN engaged in an autonomous practice must provide each new patient written information about his or her qualifications before or during the first patient encounter. Autonomous APRNs must have liability coverage of at least $100,000.00 per claim with a minimum annual aggregate of $300,000.00. This coverage is not required if an APRN: (1) practices exclusively as an officer, employee, or agent of the federal government or of the state or its agencies or subdivisions; (2) is not practicing in Florida and has an inactive registration; (3) practices only in conjunction with teaching duties at an accredited school or its main teaching hospitals; or (4) holds an active registration, but is not actively engage in autonomous practice in Florida.

The APRN must report any adverse incidents to the Department of Health ("DOH"), in writing, within 15 days of its occurrence or the discovery of its occurrence. The DOH must review the adverse incident to determine if the APRN committed any act that would subject the APRN to disciplinary action. An adverse incident as an event in which the APRN could exercise control and that is associated with a nursing intervention, which results in a condition that requires the transfer of the patient to a hospital, permanent physical injury to the patient, or death of the patient. Additionally, the Board may administratively discipline APRN for several prohibited acts related to their relationships with patients, business practices, and nursing practices.

To entice APRNs to practice in underserved communities, the DOH is authorized to pay up to $15,000.00 per year to an APRN engaging in autonomous practice that is employed to provide primary care in a public health program or an independent or group practice located in a primary care health professional shortage area serving Medicaid recipients and other low-income individuals.

Submitted by: **Timothy Wombles, Esq., and Emily Greentree, University of Florida Levin College of Law, Summer Associate*, Nelson Mullins Broad and Cassel Nelson Mullins Broad and Cassel***

REGULATORY UPDATES

Criminal Charges and TROs Related to Fraudulent COVID-19 Claims Begin

In a March 16, 2020 memorandum, Attorney General William Barr directed the United States Department of Justice ("DOJ") to prioritize fraud schemes arising out of the coronavirus emergency.[15] Below are some of the cases that the DOJ and several other federal agencies have taken up against individuals and companies seeking to profit from fraudulent COVID-19-related claims.

- Website Vaccine Claims: On March 21, 2020, the DOJ filed a civil complaint in federal court against the operators of the website "coronavirusmedicalkit.com" alleging the operators were engaging in wire fraud. The website claimed to offer consumers "access to the World Health Organization vaccine kits in exchange for a shipping charge of $4.95."[16] Since there are no legitimate COVID-19 vaccines, U.S. District Judge Robert Pitman issued a temporary restraining order (TRO) requiring the registrar of the website to immediately block public access to the site.

- Kickbacks: In March 2020, the DOJ filed a complaint against Erik Santos, asserting one count of conspiring to violate the federal Anti-kickback Statute and one count of conspiring to commit health care fraud. The complaint alleges Santos agreed to be paid kickbacks in exchange for medically unnecessary tests.[17] Specifically, Santos agreed to be paid kickbacks on a per COVID-19 test basis, "provided that those tests were bundled with a much more expensive respiratory pathogen panel test, which does not identify or treat COVID-19."[18]

- Fraudulent Claims: On April 27, 2020, a civil complaint was filed in the U.S. District Court for the District of Utah against Gordon Pedersen and his companies, My Doctor Suggests, LLC, and GP Silver, LLC. The complaint alleged the defendants were fraudulently promoting and selling products for the treatment and prevention of COVID-19. The complaint alleges the defendants made fraudulent claims, including "that having silver in the bloodstream will 'usher' any coronavirus out of the body and that 'it has been proven that Alkaline Structured Silver will destroy all forms of the viruses . . .'" and that "once in the blood stream, silver nanoparticles can block the virus from attaching to their cells, and thus 'prevent[] the disease totally and completely.'"[19] The federal court in Utah entered an injunction stopping the sale of the fraudulent COVID-19 treatments.

- Criminal Securities Claims: In June 2020, the DOJ brought its first criminal securities fraud prosecution related to COVID-19. The complaint charged Mark Schena, president of Arrayit Corporation, a publicly traded medical technology company, with one count of securities fraud and one count of conspiracy to commit health care fraud.[20] Schena/Arrayit was already involved in a conspiracy to commit health care fraud related to allergy tests.[21] Schena allegedly used "the COVID-19 pandemic as an opportunity to expand the pre-existing allergy test scheme and to capitalize on a national emergency for his own financial gain."[22] The complaint

alleges Schena "offered COVID-19 testing to obtain Medicare beneficiary information used to submit claims for Arrayit's allergy test panel, which was far more lucrative than COVID-19 testing. Arrayit promoted ordering its allergy test panel with every COVID-19 test despite the fact that it is not medically necessary to do so."[23] Furthermore, the COVID-19 test kit failed to satisfy the U.S. Food and Drug Administration ("FDA") performance standards for obtaining an emergency use authorization, and the test kits returned "false positive" results. The securities fraud charge stems from Schena's alleged misrepresentations to investors about various issues and concealment of information as to the accuracy (or lack thereof) of Arrayit's COVID-19 testing.

- Marketing False Statements: In July 2020, a federal grand jury in California indicted Huu Tieu, whose companies, Golden Sunrise Pharmaceutical, Inc., and Golden Sunrise Nutraceutical, Inc., marketed and sold herbal mixtures as COVID-19 treatments, on one count of mail fraud and one count of introducing a misbranded drug into interstate commerce with the intent to defraud. It was alleged that Tieu marketed his "Emergency D-Virus Plan of Care" to treat COVID-19 and made false statements, including that the FDA approved one of the herbal mixtures – ImunStem, specifically to treat COVID-19.[24]

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

REGULATORY UPDATES

Eleventh Circuit says "Upcoding" and "Ramping" are Material Misrepresentations under the FCA, but Failure to Create Care Plans is Not

On June 25, 2020, the Eleventh Circuit issued an important decision clarifying the materiality standard for misrepresentations under the federal False Claims Act ("FCA").[25] In 2016, the Supreme Court of the United States reframed the materiality standard under the FCA in *Universal Health Services, Inc. v. United States ex rel. Escobar*.[26] Since *Escobar*, courts have grabbled with how rigorous "materiality" as a standard should be.

In *Ruckh*, a relator, who was a registered nurse, filed a *qui tam* complaint alleging that five skilled nursing home facilities misrepresented the services they provided to Medicare beneficiaries and failed to comply with certain Medicare and Medicaid requirements by "upcoding," "ramping," and submitting claims for Medicaid reimbursement without creating or maintaining comprehensive care plans.[27]

At trial, the jury returned a verdict finding the defendants liable under the FCA.[28] The district court, after trebling damages and applying statutory penalties, entered a judgment for $347,864,285.[29] Following the entry of judgment, the defendants renewed a motion for judgment as a matter of law under Federal Rule of Civil Procedure 50(b).[30] Relying on its assessment that the relator failed to introduce evidence of materiality at trial, the district court granted the motion, set aside the jury's verdict, and granted a motion for a new trial.[31]

On appeal, the Eleventh Circuit first considered the issue of whether the relator's entry into a litigation funding agreement vitiated her standing to pursue the appeal.[32] The defendants argued that the plaintiff should not be allowed to proceed because she lacked standing under the FCA after she had agreed to sell less than 4% of her share of the judgment.[33] Despite the FCA including numerous restrictions, the Court determined that the FCA did not prohibit a relator's entry into a litigation funding agreement and, therefore, the plaintiff still had standing to proceed.[34]

The Eleventh Circuit next considered whether the district court erred in setting aside the jury's verdict because the relator failed to show evidence of materiality.[35] The Court analyzed *Escobar*, which held that a defendant can be liable under the FCA through the "false certification theory."[36] Under this theory, FCA liability attaches if (1) the alleged false claim does not merely request payment, but also makes specific representations about the goods or services provided; and (2) the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.[37] In other words, FCA liability attaches when a defendant makes misrepresentations that are "material to the Government's payment decision."[38]

Recognizing the "demanding" nature of the materiality standard, the Eleventh Circuit explained that materiality focuses on the effect that the misrepresentation has on behavior of the recipient of the alleged misrepresentation.[39] The Court further explained that materiality likely exists if a defendant knows that the government normally refuses to pay a claim because of noncompliance with a statutory, regulatory, or contractual requirement.[40] Alternatively, materiality likely does not

exist if the government normally pays a claim despite knowing that there is noncompliance with statutory, regulatory, or contractual requirements.[41]

The Eleventh Circuit then considered whether "upcoding," "ramping," and submitting claims for Medicare reimbursement without creating or maintaining comprehensive care plans were material misrepresentations.[42]

"Upcoding" is the artificial inflation of codes derived from medical assessments.[43] The defendants were accused of "upcoding" by exaggerating to Medicare the number of therapy minutes and the level of nursing services provided to residents higher than those reflected in the contemporaneous medical records.[44] The Eleventh Circuit determined that these types of affirmative misrepresentations are material because they determined the amount of Medicare reimbursement payments.[45] As a result of the misrepresentations, the defendants were paid higher amounts than what they were truly owed.[46]

"Ramping" is the timing of spikes in treatment to coincide with Medicare's regularly scheduled assessment periods, which maximizes reimbursements.[47] The defendants were accused of providing more extensive services during the look-back period than medically necessary to address patients' needs.[48] The Eleventh Circuit determined that these misrepresentations were also material because they "directly affect[] the payments Medicare" makes to the facilities.[49]

The defendants were also accused of Medicaid fraud by failing to prepare and maintain comprehensive care plans for the residents.[50] The Eleventh Circuit determined that the failure to prepare care plans was not material because care plans are, at best, labeled as conditions of payment under Medicaid regulations.[51] There also was scant evidence that the absence of care plans affected payment from the government. Additionally, the relator failed to connect the absence of care plans to specific representations defendants made about the services provided.[52]

Ultimately in *Ruckh*, the Eleventh Circuit reaffirmed that the materiality standard is rigorous and demanding. But the Eleventh Circuit slightly cleared the pathway to materiality a little more – that is, holding that "upcoding" and "ramping" are clear material misrepresentations.

Unrelated to the materiality discussion, the Eleventh Circuit also decided that proximate cause was the appropriate causation standard for "cause to be presented" claims, which is a theory of FCA liability.[53] A defendant's conduct may be found to have caused the submission of a false claim if the conduct was (1) a substantial factor in inducing providers to submit claims for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct.[54]

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

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[1] *See Dep't of Health, Emergency Med. Oversight v. Litsch*, Case No. 18-2891PL at *18 (Fla. Div. of Admin. Hearing Sept. 12, 2018) (the ALJ recommended, among other things, that the Respondent's paramedic license be suspended, as a result of a default on his student loans, until new loan payment terms were agreed upon.).
[2] *H.B. 713 Staff Analysis*, Fla. House of Representative's Health and Human Services Committee 13 (Feb. 13, 2020).

[3] *Id.*
[4] Ch. 2020-125 § 3, Laws of Fla.
[5] Section 456.074(4), Florida Statutes, prior to being repealed, stated:

> Upon receipt of information that a Florida-licensed healthcare practitioner has defaulted on a student loan issued or guaranteed by the state or the Federal Government, the department shall notify the licensee by certified mail that he or she shall be subject to immediate suspension of license unless, within 45 days after the date of mailing, the licensee provides proof that new payment terms have been agreed upon by all parties to the loan. The department shall issue an emergency order suspending the license of any licensee who, after 45 days following the date of mailing from the department, has failed to provide such proof. Production of such proof shall not prohibit the department from proceeding with disciplinary action against the licensee pursuant to s. 456.073.

[6] Ch. 2020-125 § 5, Laws of Fla; Ch. 2020-133 § 12, Laws of Fla.
[7] FLA. STAT. § 744.441(2).
[8] *Id.* § 744.363(1)(f).
[9] *Id.*
[10] *Id.*
[11] HR 6971 can be accessed at: https://www.congress.gov/116/bills/hr6971/BILLS-116hr6971ih.pdf.
[12] Sec. 1861, Social Security Act, can be accessed at https://www.ssa.gov/OP_Home/ssact/title18/1861.htm.
[13] *Leading Causes of Death*, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm.
[14] *Health and Economic Costs of Chronic Diseases*, Centers for Disease Control and Prevention, https://www.cdc.gov/chronicdisease/about/costs/index.htm#ref6.
[15] Memorandum, U.S. Dep't of Justice, COVID-19 – Department of Justice Priorities (Mar. 16, 2020), https://www.justice.gov/ag/page/file/1258676/download.
[16] Press Release, U.S. Dep't of Justice, Justice Department Files Its First Enforcement Action Against COVID-19 Fraud (Mar. 22, 2020), https://www.justice.gov/opa/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud.
[17] Santos was already involved in an anti-kickback scheme to be paid per test for genetic cancer screenings.
[18] Press Release, U.S. Dep't of Justice, Georgia Man Arrested for Orchestrating Scheme to Defraud Health Care Benefit Programs Related to COVID-19 and Genetic Cancer Testing (Mar. 30, 2020), https://www.justice.gov/usao-nj/pr/georgia-man-arrested-orchestrating-scheme-defraud-health-care-benefit-programs-related.
[19] Press Release, U.S. Dep't of Justice, Court Orders Halt to Sale of Silver Product Fraudulently Touted as COVID-19 Cure (Apr. 29, 2020), https://www.justice.gov/opa/pr/court-orders-halt-sale-silver-product-fraudulently-touted-covid-19-cure.
[20] Complaint at __, *U.S. v. Schena*, No. CR 20-70721-MAG (N.D. Cal. filed June 8, 2020), https://www.justice.gov/opa/press-release/file/1283931/download.
[21] Arrayit allegedly ran a full test panel of 120 allergens every time for every patient without regard to medical necessity. Additionally, Arrayit paid physician illegal kickbacks in exchange for their NPI number to submit claims for testing for patients that the physician never saw.
[22] Karen S. Lovitch & Rachel E. Yount, *DOJ Announces Criminal Charges Against Lab Executive Accused of Fraudulent Promoting COVID-19 Tests*, National Law Review, https://www.natlawreview.com/print/article/doj-announces-criminal-charges-against-lab-executive-accused-fraudulently-promoting?utm_content=89fb7fe6e2c5e65e18751a82a37e7626&utm_campaign=2020-6-26%20Healthcare%20Legal%20News&utm_source=Robly.com&utm_medium=email.
[23] *Id.*
[24] *California Man Faces Federal Criminal Charges for Marketing Herbal Mixture as COVID-19 Treatment*, American Health Law Association, https://www.americanhealthlaw.org/content-library/health-law-weekly/article/1c505f14-2a35-4e35-b1da-d6cd61c5edf1/California-Man-Faces-Federal-Criminal-Charges-for
[25] *Ruckh v. Salus Rehabilitation, LLC*, 963 F.3d 1089 (11th Cir. 2020).
[26] 579 U.S. –, 136 S. Ct. 1989, 195 L. Ed. 2d 348 (2016).
[27] *Ruckh*, 963 F.3d at 1097.
[28] *Id.* at 1098.
[29] *Id.*

[30] *Id.*
[31] *Id.* at 1098-1099.
[32] *Id.* at 1100.
[33] *Id.*
[34] *Id.* at 1102.
[35] *Id.* at 1103.
[36] *Id.*
[37] *Id.* at 1103-1104.
[38] *Id.* at 1104.
[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.* at 1097.
[44] *Id.* at 1104-1105.
[45] *Id.* at 1105.
[46] *Id.* at 1105.
[47] *Id.* at 1097.
[48] *Id.* at 1105.
[49] *Id.* at 1106.
[50] *Id.* at 1108.
[51] *Id.*
[52] *Id.*
[53] *Id.* at 1107.
[54] *Id.*