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HEALTH LAW DISPATCH

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COVID-19

Regulatory Response to COVID-19 Expands the Frontlines of Care

By Divya Srivastav-Seth, Esq.

The COVID-19 pandemic has caused federal and state governments to fast-track the removal of existing regulatory restrictions in order to enable health care providers to meet the unprecedented medical needs of the public. Telehealth and telemedicine services have been catapulted to the frontlines of care in order to limit the risk of exposure and facilitate care. In addition, other measures have been implemented to provide the flexibility and resources necessary to address the crisis. The following is a summary of some these measures.

I. FEDERAL ACTIONS

A. CPRSA and Cares Acts (Medicare Covered Telehealth Services)

The "Coronavirus Preparedness and Response Supplemental Appropriations Act" (P.L.116-23) ("CPRSA") and the "Coronavirus Aid, Relief, and Economic Security Act" (H.R.748) ("CARES Act") authorized the waiver of Medicare regulatory restrictions for telemedicine and telehealth services during the period of the emergency as follows:

- **Geographic/Site Limitations.** Prior to the changes, Medicare reimbursement was only available for telehealth services if they were provided to an eligible beneficiary located in a physician's office or other authorized healthy facility which is also in a designated rural area. The law now provides that for the duration of the emergency, Medicare will pay for these services if rendered by a qualified health care provider to a beneficiary in any region of the country and at any location including the patient's home, provided that such region and home are in an emergency area.

- **Patient Provider Relationship.** The CARES Act also relaxed the requirement that the provider and the patient have an established relationship.

- **Qualified Providers.** The CARES Act added Federally Qualified Health Centers/Rural Health Clinics (during the emergency period only) to the providers eligible to provide telehealth services.

- **Removal of Face-to-Face for Home Dialysis.** The CARES Act also removes the requirement for periodic face-to-face visits between providers and patients receiving home dialysis as a condition for receiving telehealth services.

- **Services.** All services that are currently available under the Medicare telehealth reimbursement policies are included in the waiver without regard to the beneficiary's diagnosis of COVID.

- **Cost Sharing.** Out-of-pocket charges such as co-insurance and co-pays still apply but the Office of the Inspector General has issued guidance stating that it will not impose sanctions if any health care provider chooses not to collect these fees for telehealth visits. See https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf.

- **Modality.** Medicare requires that an interactive audio and video telecommunications system that permits real-time communication be used as a condition for payment. CPRSA explicitly allowed for the use of phones that have audio and video capabilities for the furnishing of Medicare telehealth services, but the CARES Act removed this specific language.

B. Health Insurance Portability and Accountability Act (HIPAA) COVID Waivers

- **HIPAA Waivers for Telehealth.** The Office for Civil Rights ("OCR") has also issued a Notice of Enforcement

Discretion stating that it will waive penalties for HIPAA violations against health care providers that serve patients in good faith through everyday non-public facing communications technologies, during the COVID-19 nationwide public health emergency. See https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf.

- **HIPAA Waivers for Covered Hospitals.** For the period of the emergency, OCR has also said that it would waive sanctions and penalties against a covered hospital that does not comply with the following provisions of the HIPAA Privacy Rule: (i) the requirement to obtain a patient's agreement to speak with family members or friends involved in the patient's care (See 45 CFR 164.510(b)); (ii) the requirement to honor a request to opt out of the facility directory (See 45 CFR 164.510(a)); (iii) the requirement to distribute a notice of privacy practices (See 45 CFR 164.520); (iv) the patient's right to request privacy restrictions (See 45 CFR 164.522(a)); and (v) the patient's right to request confidential communications (See 45 CFR 164.522(b)). The waiver became effective on March 15, 2020 and only applies: (1) in the emergency area identified in the public health emergency declaration; (2) to hospitals that have instituted a disaster protocol; and (3) for up to 72 hours from the time the hospital implements its disaster protocol. When the emergency declaration terminates, a hospital must then comply with all the requirements of the Privacy Rule for any patient still under its care, even if 72 hours have not elapsed since implementation of its disaster protocol. See https://www.hhs.gov/sites/default/files/hipaa-and-covid-19-limited-hipaa-waiver-bulletin-508.pdf.

C. Skilled Nursing Facilities ("SNF") Waivers

The waiver provides Medicare coverage for SNF care without a three-day inpatient hospital stay for beneficiaries who experience dislocations or are otherwise affected by the COVID emergency, including those who (1) are evacuated from a nursing home in the emergency area; (2) are discharged from a hospital in order to provide care to more seriously ill patients; or (3) need SNF care as a result of the emergency, regardless of whether they were in a hospital or nursing home prior to the emergency. In addition, CMS will recognize special circumstances for certain beneficiaries and will waive the requirement of establishing a new benefit period (i.e., breaking the spell of illness by being discharged to a custodial care or noninstitutional setting for at least 60 days), and thus will cover additional SNF care for certain beneficiaries without requiring a break in the spell of illness for those beneficiaries in connection with the emergency.

II. NEW JERSEY STATE ACTIONS

A. Medicaid and Carriers Telehealth Coverage (P.L.2020, c.7.)

This law requires the State Medicaid programs and any carrier that offers a health benefits plan to provide coverage and payment for expenses incurred in: (1) the testing for COVID-19, provided that a licensed medical practitioner has issued a medical order for that testing and (2) the delivery of health care services through telemedicine or telehealth. The law directs that the coverage for the services be provided to the same extent as for any other health care services except that no cost-sharing shall be imposed on the coverage for telehealth services.

B. Modalities

The New Jersey State Department of Banking and Insurance (DOBI) has issued a bulletin (See AV COVID-19 Telemedicine and Telehealth Bulletin 20-07, March 22, 2020), which states that "[c]arriers are not permitted to impose any specific requirements on the technologies used to deliver telemedicine and/or telehealth services (including any limitations on audio-only or live video technologies) during the state of emergency and further requires carriers *inter alia* to update their policies to include if clinically appropriate, that telehealth services may be conducted by telephone in order to minimize exposure of the COVID-19 virus."

C. Out of State Providers (P.L.2020, c.3.)

The new law provides that for duration of the emergency an out of state health care practitioner in possession of a valid license in another state may provide telehealth services if these services are within the practitioner's authorized scope of practice unless the health care practitioner has a preexisting provider-patient relationship with the patient that is unrelated to COVID-19. In the event that the health care practitioner determines during a telehealth encounter with a patient located in New Jersey that the encounter will not involve COVID-19, and the practitioner does not have a preexisting provider-patient relationship with the patient that is unrelated to COVID-19, the practitioner shall advise the patient that the practitioner is not authorized to provide services to the patient, recommend that the patient initiate a new

telehealth encounter with a health care practitioner licensed or certified to practice in New Jersey, and terminate the encounter.

D. Elective Surgeries (NJ Executive Order 109)

Executive Order 109 (the "Order") suspended as of Friday March 27, 2020, all "elective" surgeries or invasive procedures performed on adults, whether medical or dental, provided that the delay can take place without undue risk to the current or future health of the patient as determined by the patient's treating physician or dentist. The Order also directs each hospital or ambulatory surgery center to establish written guidelines to ensure adherence to its provisions and send a copy to the New Jersey Department of Health. In establishing such guidelines, the hospital or ambulatory surgery center shall include a process for consultation with the treating provider about a designation that the surgery or invasive procedure is elective under the terms of this Order. Facilities are to immediately notify all patients and providers that these operations cannot proceed as scheduled under the terms of this Order. Nothing in the Order is to be construed to limit access to the full range of family planning services and procedures, including terminations of pregnancies, whether in a hospital, ambulatory surgery center, physician office, or other location.

Due to the emergent nature of the virus and the rapidly changing legal and regulatory landscape, we will continue to monitor developments and health care professionals may contact Divya Srivastav-Seth, Esq. at dss@spsk.com or 973-631-7855 or any other member of Schenck Price's Health Care Law Practice Group for more information.

Beyond COVID-19

CIRCUIT COURT SPLIT: What Does the Third Circuit's Ruling in *United States v. Care Alternatives* Mean for Provider Liability Under the FCA?

By Evan B. Magnone, Esq.

On March 4, 2020, the United States Court of Appeals for the Third Circuit decided a matter of first impression in U.S. v. Care Alternatives, No. 18-3298, 2020 WL 1038083 (3d Cir. 2020) holding that conflicting medical opinions can create a genuine dispute of material facts as to the elements of falsity in an action pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33.

Factual Background

Former employees of defendant hospice provider alleged that Care Alternatives admitted patients who were ineligible for hospice care and then directed its employees to improperly alter those patients' Medicare certifications to reflect eligibility by means of a terminally ill prognosis of six months or less. Generally, Medicare will only pay hospice benefits for individuals who are certified by a physician as having a terminal prognosis of six months or less.

Both parties' experts disagreed whether a reasonable physician would have certified the patients as having a terminally ill prognosis of six months or less. In support of its motion for summary judgment, Care Alternatives alleged that the difference of opinion between the experts was insufficient to create a triable dispute of fact as to the element of falsity under the FCA.

District Court's Opinion

The District Court agreed with Care Alternatives and, in citing the Eleventh and Fifth Circuits, held that a mere difference of opinion between the parties' experts was insufficient to create a triable dispute of fact as to the element of falsity under the FCA. See U.S. v. AseraCare Inc., 938 F.3d 1278 (11th Cir. 2019) (upholding an "objectively false" standard and the premise that medical opinions are subjective and cannot be "false" for the purpose of FCA liability); See also U.S. ex rel. Wall v. Vista Hospice Care, Inc., 2018 WL 3054767 (5th Cir. Jan. 11, 2018).

Reversal by the Third Circuit

On appeal, the Third Circuit reversed and held that the parties' conflicting expert opinions was sufficient to create a genuine issue of fact as to the element of falsity under the FCA, and that the District Court improperly incorporated a scienter element into its analysis. The Third Circuit wanted to make clear that findings of falsity and scienter must

be independent from one another for purposes of FCA liability. The Third Circuit found that an expert opinion that differed from the certifying physician's opinion was relevant evidence as to whether there was evidence of legal falsity.

What does this mean for providers in the Third Circuit?

Not only has the Third Circuit now created a split between the Circuits (potentially laying the groundwork for an appeal to the Supreme Court) but the issue of falsity in FCA cases is, at least for now, a question for the jury to decide when there are conflicting medical opinions. Hospice and healthcare providers in the Third Circuit can no longer insulate themselves from FCA liability based on a physician's reasonable opinion alone.

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New Jersey Supreme Court Affirms Protection for Employees Using Medical Marijuana

By Meghan V. Hoppe, Esq.

On March 10, 2020, the New Jersey Supreme Court affirmed the reinstatement of a disability discrimination lawsuit filed by a medical marijuana patient against his former employer for failing to accommodate his out-of-office medical marijuana use after he was purportedly fired for failing a drug test. See Wild v Carriage Funeral Holdings, Inc., 2020 N.J. LEXIS 299 (Mar. 10, 2020). The Appellate Division held last March that plaintiff Justin Wild ("Wild") had adequately pled a cause of action against his former employer for violation of the New Jersey Law Against Discrimination ("NJLAD"). As we previously wrote about in our September 2019 Legal Updates for Businesses, Wild was prescribed medical marijuana to treat cancer pursuant to the New Jersey Compassionate Use of Medical Marijuana Act ("CUMMA").

The Court substantially adopted the Appellate Division's reasoning but declined to adopt the view that CUMMA "intended to cause no impact on existing employment rights." While the Court agreed that there is no conflict between CUMMA and NJLAD, it noted that there would be no basis for the NJLAD claim had the legislature not enacted CUMMA, which authorized Wild's use of medical marijuana outside of the workplace. The Court added that two provisions of CUMMA may affect the viability of a medical marijuana discrimination claim or failure to accommodate claim under NJLAD: (1) CUMMA does not require an employer to accommodate an employee's use of medical marijuana in the workplace and (2) CUMMA does not permit any person to "operate, navigate or be in actual physical control of any vehicle, aircraft, railroad train, stationary heavy equipment or vessel while under the influence of marijuana."

At the time that Wild filed the lawsuit, CUMMA did not provide employment protections to authorized users of medical marijuana. However, CUMMA was amended after the Appellate Division's decision to expressly prohibit employers from taking adverse employment actions against employees "based solely on the employee's status" as a medical marijuana user. The Court applied the provisions of CUMMA as they existed prior to the 2019 amendments.

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CMS and ONC Rules Give Patients More Control of Health Data

By Deborah A. Cmielewski, Esq.

The U.S. Department of Health and Human Services has finalized two new rules (the "Final Rules") designed to further enable patients to access and control their health care data. These separate but related rules, issued by the Office of the National Coordinator for Health Information Technology ("ONC") and the Centers for Medicare & Medicaid Services ("CMS"), represent another substantial effort toward facilitating patient access to medical information, as prescribed by the 21st Century Cures Act and Executive Order 13813.

The Final Rules are touted as the most extensive health care data sharing policies ever to be implemented by the federal government. They will, in large part, enable patients to manage and shop for their health care using smartphone apps, in much the same manner that they manage other elements of their lives, such as travel and financial information.

The ONC Final Rule includes new standards to prevent information blocking by health care providers, information technology ("IT") developers and others; exceptions to the standards for information blocking; updated standards and certification requirements for developers of health IT; and requirements for electronic health records to provide data essential to promoting new business models of care. In addition, the ONC Final Rule sets forth application programming interface ("API") requirements to facilitate patient access to their health information electronically and free of charge, using smartphone apps.

The CMS Final Rule includes key components that enable patients to move swiftly through the health system. The Rule requires health plans in Medicare Advantage, Medicaid, Children's Health Insurance Program (CHIP) and the federal exchanges to provide patients with electronic access to their claims and other health data through a secure and user-friendly patient access API. Moreover, it facilitates patient movement through the health system by including a new Condition of Participation (CoP) for hospitals participating in Medicare and Medicaid to electronically notify other health care practitioners when a patient is transferred, admitted or discharged.

Now more than ever patients have a crucial need for immediate access to their health information. In the wake of the COVID-19 pandemic, such access can have lifesaving consequences for patients facing health crises.

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EEOC Alleges That Hospital's "Late Career Practioner Policy" Violates Federal Law

By Brian M. Foley, Esq.

The U.S. Equal Employment Opportunity Commission (the "EEOC") filed a lawsuit against Yale New Haven Hospital (the "Hospital") on February 11, 2020, alleging that its "Late Career Practitioner Policy" violates federal law. The action, EEOC v. Yale New Haven Hospital, Civil Action No. 3:20-cv-00187, is pending in the U.S. District Court for the District of Connecticut. The Hospital is the primary teaching hospital for the Yale University School of Medicine. The Policy is similar to Late Career Practitioner Policies that have been adopted by many other hospitals throughout the country. As such, the final decision in this matter will have wide ranging ramifications.

The Policy provides that any individual age 70 or older who applies for or seeks the renewal of medical staff privileges at the Hospital must take both an ophthalmologic and a neuropsychological medical examination. Individuals and employees younger than age 70 are not subject to this Policy. According to the complaint, since implementing the Policy in 2016, approximately 145 individuals had been subject to the Policy, and at least seven had been identified as "failed."

The EEOC alleges that the Policy violates the Age Discrimination in Employment Act ("ADEA"), 29 U.S.C. § 621; the Americans with Disabilities Act ("ADA"), 42 U.S.C. § 12191; and the Civil Rights Act of 1991, 42 U.S.C. § 1981a. The EEOC seeks compensatory and punitive damages, as well as injunctive relief which includes the elimination of the Policy. The EEOC alleges violations of the ADEA as "those subject to the Policy are required to be tested solely because of their age, without any suspicion that their neuropsychological ability may have declined." According to the EEOC, "by subjecting only these older applicants and employees to the Policy, the Hospital violates the ADEA." Additionally, the EEOC alleges the Policy violates the ADA, citing its prohibitions against subjecting employees to medical examinations that are not job-related and consistent with business necessity.

Although the Hospital has not yet filed a formal answer to the complaint, it has said that the Policy "is designed to protect patients from potential harm while including safeguards to ensure that physicians are treated fairly." According to the Hospital, "the Policy is modeled on similar standards in other industries... we are confident that no discrimination has occurred and will vigorously defend ourselves in this matter."

Like many hospitals, medical staffs and physicians throughout the country, we will keep a close eye on this matter, and we will alert our clients on future developments.

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RECENT HEALTH LAW LEGAL ALERTS

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