Schenck Price
SCHENCK PRICE SMITH & KING, LLP
www.spsk.com

HEALTH LAW DISPATCH

August 2019

Update

New Jersey Supreme Court Allows Death with Dignity Law to Remain in Effect

By Divya Srivastav-Seth, Esq.

On August 27, 2019, the New Jersey Supreme Court weighed in on the controversy roiling the lower courts regarding the temporary stay placed on the Medical Aid in Dying for the Terminally Ill Act (P.L.2019, c. 59, N.J.S.A. 26:16-1, et seq.) ("Act") and permitted the Act to take effect. See Glassman v. Grewal, Attorney General of the State of New Jersey, N.J. Sup. Ct., Dkt. No. 083382, August 27, 2019).

The Act allows a qualified, mentally capable, terminally ill adult to request a doctor's prescription for the self-administration of medication which will result in the patient's death. The Act went into effect on August 1, 2019. The first compliant prescription under the Act's statutory time limits and procedural framework could have been written on August 16, 2019. However, shortly after the Act's effective date, this timeline was stayed when a physician filed an emergent motion for a temporary restraining order staying the Act's implementation based on allegations that the public was at risk of imminent and irreparable harm. The motion was made in the context of the physician's underlying lawsuit for a declaratory judgment and permanent injunction of the Act on the grounds that it violated constitutional protections. In addition, the physician also contended that the failure of the various administrative agencies with rulemaking authority under the Act to provide any guidance or implement any regulations created a dangerous vacuum and violated the Administrative Procedure Act. See Glassman v. Gurbir Grewal, Attorney General of State of New Jersey (Superior Court, Chancery Division, Mercer County filed August 9, 2019, Dkt. No. MER-C-53-19). The Chancery Court did not put much stock in the constitutional arguments due to the physician's lack of standing but awarded the temporary stay due to the fact that administrative agencies had failed to act despite the material change in the treatment of terminally ill patients.

On appeal, the Appellate Division reversed the stay on the grounds that the lower court had abused its discretion because the general failure of the administrative agencies to adopt enabling regulations was not sufficient to show irreparable harm without further proof of how this deficiency harmed the physician, irreparably or otherwise. Further, the Appellate Division noted that administrative agencies are given wide latitude to effectuate their regulatory jurisdiction and that the absence of regulation could imply that further rulemaking was actually not necessary. The Appellate Court also found that nothing in the Act indicated that the Legislature intended for the Act's implementation to await formal rulemaking. Therefore, the Appellate Division vacated the temporary stay and remanded the matter back to the Chancery Court for further proceedings.

The physician then sought emergent relief from the New Jersey Supreme Court which immediately issued an order that upheld the Appellate Division's removal of the temporary stay. Accordingly, the Act is currently in effect. The underlying lawsuit seeking a permanent injunction is still pending in the lower courts.

For more information, contact Divya Srivastav-Seth, Esq. at dss@spsk.com or 973-631-7855.

New Jersey Expands Medical Marijuana Law

By Meghan V. Hoppe, Esq.

On July 2, 2019, Governor Phil Murphy signed the Jake Honig Compassionate Use Medical Cannabis Act (the "Act") into law. The Act amends the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:61-2, et seq. and formally changes its name to the Jake Honig Compassionate Use Medical Cannabis Act. The Act substantially expands and reforms New Jersey's Medicinal Marijuana Program ("MMP")

thereby increasing patient access to medical marijuana.

The Act makes several statutory changes to New Jersey's MMP. Some of the significant changes include:

- Creating a Cannabis Regulatory Commission that will oversee, administer, and enforce New Jersey's MMP.
- Increasing the quantity of medical marijuana that can be purchased from 2 ounces to 3 ounces for 18 months, and after that time elapses, the maximum amount will be determined by regulation. Terminally ill and hospice care patients will not be subject to any monthly limit.
- Phasing out the sales tax on medical marijuana over the next three years; sales tax will fall to 4% in July 2020, 2% in July 2021 and be eliminated entirely in July 2022.
- Allowing physician assistants and advanced practice nurses, in addition to physicians, to authorize medical marijuana treatments.
- Prohibiting employers from taking adverse employment actions against employees solely based on their status as medical marijuana patients (i.e., for off premises and non-working hour consumption of medical marijuana).
- Authorizing patients to have two designated caregivers who can obtain medical marijuana for the patient.
- Permitting reciprocity with other states' medical marijuana programs that will allow out-of-state patients permission to buy medical marijuana while visiting New Jersey for a period of up to 6 months.
- Authorizing the adoption of regulations to enable dispensaries to deliver medical marijuana to patients at home.

The Act also requires the Cannabis Regulatory Commission to issue a request for new permit applications and sets up new categories of permits, including cultivators, manufacturers and dispensaries. The Act restricts the number and type of permits that will be awarded within the first 18 months of the effective date of the Act. For instance, entities may only be awarded one type of permit (i.e., cultivator, manufacturer or dispensary) and the number of cultivator permits is currently capped at 28.

For more information, contact Meghan V. Hoppe, Esq. at mvh@spsk.com or (973) 540-7351.

SAMHSA Issues Proposed Changes to Part 2 Rules to Facilitate Information Sharing

By Deborah A. Cmielewski, Esq.

On August 22, 2019, the Substance Abuse and Mental Health Services Administration ("SAMHSA") issued a long-awaited proposal to modify the rules relating to the confidentiality of substance use disorder ("SUD") records codified at 42 C.F.R. Part 2 (the "Part 2 Rules") to facilitate the sharing of information for care coordination purposes. The proposal represents a key effort by the Trump Administration towards combating the opioid crisis that continues to plague the nation, and is the first step in the Sprint to Coordinated Care Initiative, launched by the United States Department of Health and Human Services ("HHS") in 2018.

Proponents of the care coordination effort sought to harmonize the Part 2 Rules with HIPAA and to facilitate the sharing of SUD information for treatment, payment and health care operations purposes. The proposal falls short of that goal, by leaving intact the requirement that patients must consent to information sharing for such purposes, absent limited exceptions as authorized by statute, such as a bona fide medical emergency.

Some key elements of the proposal include less strenuous consent requirements for information sharing in limited circumstances as well as greater information exchange in certain emergencies. One important element of the proposal permits SUD patients to consent to disclose their SUD records to a variety of entities, such as the Social Security Administration, local sober living facilities and halfway houses, without the current requirement of identifying a specific individual who will receive the information. The proposal enables patients to designate the entity as a whole as the recipient of SUD information, which may enable patients to access resources and benefits with greater ease. The proposal also enables providers to disclose SUD records to another Part 2 program or treatment provider without consent in the event of a temporary state of emergency declared by a state and/or federal authority due to a natural or major disaster. Under the proposal, such events will meet the definition of a "bona fide medical emergency" and facilitate continuity of care in times of grave need. In addition, the proposal clarifies that the recording of SUD information and the treatment of SUD by a non-Part 2 provider, as well as the possession of Part 2 records by such provider does not, on its own, subject the entity to

the requirements of Part 2. In that regard, the non-Part 2 entity would be required to segregate the SUD records from other treatment records.

The proposal comes on the heels of correspondence recently directed to congressional leadership by the National Association of Attorneys General ("NAAG"). That letter, signed by 39 Attorneys General throughout the United States, urged Congress to remove federal barriers to treatment and sharing of information, noting that the opioid crisis has had a negative effect on overall life expectancy in the United States and contributed to a rise in health conditions, such as Hepatitis C and drug withdrawal in newborns. While the proposal is a step toward greater coordination of care, it fails to accomplish a complete reform of the Part 2 Rules.

The proposal appeared in the August 26, 2019 Federal Register. Interested parties may submit written comments by no later than October 25, 2019.

For more information, contact Deborah A. Cmielewski, Esq. at dac@spsk.com or 973-540-7327.

A Corporate Practice of Medicine Reminder

By Daniel O. Carroll, Esq.

A recent decision by New York's highest court is the latest reminder for physicians in the New York and New Jersey area to take care when structuring their business ventures to ensure compliance with corporate practice of medicine restrictions related to ownership and control of a physician's practice. The Court held that payors can withhold amounts due to a provider if the provider gives too much control over his/her practice to unlicensed individuals or entities providing management services to such provider's practice thereby violating corporate practice of medicine restrictions. See Andrew Carothers, M.D., P.C. v. Progressive Ins. Co., 33 N.Y.3d 389 (2019) (explaining State Farm Mut. Auto. Ins. Co. v. Mallela, 4 N.Y.3d 313 (2005)).

The Carothers Court noted that it is well-settled in New York that an insurance company can withhold reimbursement for claims filed by "fraudulently incorporated enterprises" and clarified in its holding that "fraudulently incorporated" does not actually require proof of fraud but rather a finding of "willful and material failure to abide by" licensing and incorporation statutes is enough to make a provider ineligible for reimbursement. It is sufficient to find that the professional corporation circumvented the corporate practice of medicine restrictions by giving too much control to non-physicians and could result in professional services effectively being provided by unlicensed individuals who may prioritize monetary interests over patient care.

The Carothers case should remind New Jersey physicians of the New Jersey Supreme Court's 2017 holding in Allstate Ins. Co. v. Northfield Med. Ctr, P.C., 228 N.J. 596 (2017), which similarly applied New Jersey's well-established corporate practice of medicine regulatory prohibitions and restrictions governing ownership and control of a medical practice by a non-physician (whether unlicensed or lesser license). The Northfield case illustrates what the New Jersey Supreme Court deems to be an unacceptable practice structure for physicians intentionally giving an excessive and impermissible degree of control over the physician practice to individuals other than the licensed physicians (such as management services providers) in order to protect the business investment of such non-physicians. The decision makes clear that physicians may not structure their business arrangements and operate their practice in a manner that may subjugate their ability to exercise professional judgment for patient care to the control of non-physicians (such as management service providers) without potentially running afoul of New Jersey's corporate practice of medicine regulation and violating New Jersey's Insurance Fraud Prevention Act, N.J.S.A. 17:33A-1, et seq.

Physicians and management service providers should seek the advice of legal counsel when structuring and entering into arrangements to ensure control of the physician practice is not impermissibly transferred to non-physicians in violation of corporate practice of medicine restrictions established under state law.

For more information, Daniel O. Carroll, Esq. at doc@spsk.com or 973-631-7842.

RECENT HEALTH LAW LEGAL ALERTS

New Jersey Enters Multistate Nurse Licensure Compact

New Jersey Continues Battle Against Opioid Epidemic