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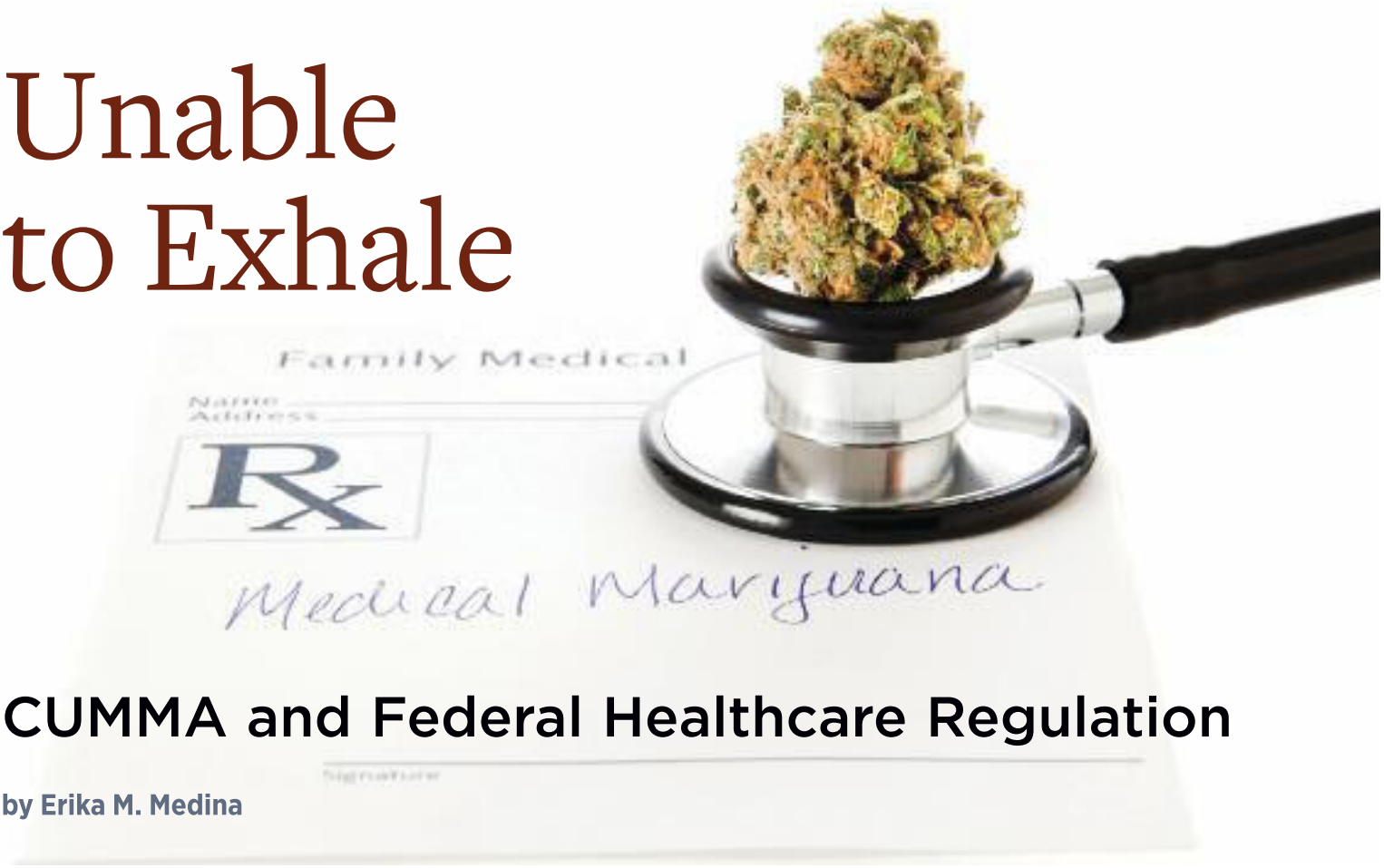

CUMMA and Federal Healthcare Regulation

by Erika M. Medina

ERIKA M. MEDINA *is an ERISA associate at Cohen, Weiss and Simon, LLP, where she counsels clients on the operation and administration of employee benefit plans. Prior to joining Cohen Weiss, Medina was ERISA counsel for USI Insurance Services, LLC (USI), supporting the brokerage and consulting businesses of the Northeast Region. She was also a senior investigator at the U.S. Department of Labor, Employee Benefits Security Administration, where she conducted complex civil and criminal investigations of employee benefit plans, service providers, and financial institutions to ensure compliance with ERISA.*

The New Jersey Compassionate Use Medical Marijuana Act (CUMMA)[1] protects patients who use marijuana to alleviate suffering caused by debilitating medical conditions from criminal prosecution and civil penalties. Dependent on the disease causing the debilitating medical condition and through an assessment, a physician may authorize the use of medical marijuana. However, because marijuana is federally classified as having no medical value and a high potential for abuse, limitations are placed on the coverage of medical marijuana provided by health plans.

To obtain access to medical marijuana, an individual must perform three steps: 1) visit a physician; 2) obtain an authorization for medical marijuana; and 3) purchase marijuana from an authorized treatment center. The individual is eligible to purchase marijuana if he or she is a qualifying patient,[2] defined as a New Jersey resident who has received a certification from a physician pursuant to a *bona fide* physician-patient relationship. The *bona fide* physician-patient relationship[3] is established through an on-going relationship between a qualifying patient and a physician to assess, care for and treat a debilitating medical condition.[4]

The costs of physician visits to establish a *bona fide* physician-patient relationship are covered by the health plan per the terms of the plan documents. The Affordable Care Act (ACA) requires a health plan to cover preventive health services at no cost to the participant.[5] Preventive care is defined as an item or service that has a rating

of A or B in the recommendations made by the United States Preventive Services Task Force (USPSTF).[6] For example, breast cancer screening is recommended for women between the ages of 50-74 and has a B rating by the USPSTF. Thus, the breast cancer screening and related physician visits must be covered by all health plans at no cost to the patient. Thereafter, if the patient is diagnosed with breast cancer, the patient visits to care and treat the cancer are covered by the health plan per the terms of the plan document. Generally, a health plan will cover such visits if medically necessary. The initial physician visit to assess a condition and the subsequent visits to care for and treat the condition establish the *bona fide* physician-patient relationship, as required by CUMMA.

Once the *bona fide* physician-patient relationship is established, the patient may seek authorization from the physician to use marijuana. The physician visit to obtain the authorization may be covered if the physician visit is to care for or treat the medical condition in addition to obtaining an authorization. However, if the visit is merely to obtain an authorization from the physician (*i.e.*, a stand-alone authorization visit), the visit is not required to be covered by the health plan unless the terms of the plan document permit the coverage. Most fully insured health plans underwritten in the state of New Jersey will not cover the visits because state insurance provisions do not require their coverage. Nevertheless, self-insured plans may extend health coverage of authorization visits.

Depending on the health plan, experimental or investigational treatment may be covered and, thus, may extend coverage to a stand-alone authorization visit. Experimental or investigational limitations are not defined by federal law; rather, they are designed by health plans or issuers.[7] Most experimental or investigational limitations will limit all treatment unless it meets specific criteria established by the health plan, such as therapies approved by the Food and Drug Administration (FDA), scientific reviews, or clinical trials. If the guidelines require FDA approval or review, the health plan will exclude an authorization visit. However, if the guidelines rely on any medical research, the authorization visit may be covered, as there are currently five states developing medical research of marijuana that may potentially be relied upon: Florida, Georgia, Louisiana, New York and Pennsylvania.[8]

Once a patient has received an authorization to use marijuana, he or she must purchase the marijuana from an authorized treatment center, and the purchase cannot be covered by the health plan. Marijuana is classified as a narcotic[9] by the Controlled Substances Act of 1970 (CSA), which requires the involvement of various federal agencies to conduct research. The FDA is in charge of reviewing products intended to diagnose, cure, mitigate, treat or prevent a disease and, upon confirmation, classifying the product as a drug. Due to marijuana's current classification and strict research requirements, the FDA has been unable to approve marijuana for any medical use.[10] Thus, under federal law, marijuana is not a drug and cannot be prescribed by a physician. As such, the CUMMA does not permit the prescription of marijuana, but allows a physician to authorize its use. As a result, a health plan would be unable to cover the cost of marijuana as a prescription because it is not classified as a drug.

Similarly, the cost of marijuana cannot be covered as a medical service or medical device. If a health plan covers medical care, it will also be required to cover medical devices necessary for the treatment or care of the illness. A medical device[11] is an instrument, apparatus, or other similar item that is recognized by the National Formulary, intended for use in the diagnosis of a disease or condition, or intended to affect the structure or any function of the body, which does not achieve its purpose through chemical action. Because marijuana achieves its intended use through chemical action, it cannot be a medical device, but must meet the drug requirements. Moreover, marijuana is not considered medical care because it is specifically excluded by the Internal Revenue Service (IRS). Section 213 of the Internal Revenue Code (IRC) defines medical care as amounts paid for the "diagnosis, cure, mitigation, treatment or prevention of a disease…"[12] While it may be argued that marijuana is medical care because it is used to treat a disease, the IRS has excluded it as a permitted medical expense through sub-regulatory guidance[13] due to marijuana's classification as a controlled substance.

After use of marijuana, if a patient experiences complications the health plan is required to treat the complication if the plan otherwise covers the underlying medical condition. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) prohibits health plans and issuers from discriminating against individuals based on health status.[14] HIPAA requires benefits to be uniformly available and restrictions to be applied uniformly to similarly situated individuals. HIPAA permits certain exclusions, such as coverage of certain drugs or treatments, coverage based on medical necessity or experimental treatment, or cost-sharing limits. Moreover, HIPAA permits health plans and issuers to exclude coverage based on the source of injury, except if the injury results from domestic violence or a medical condition.[15] Thus, health plan provisions that exclude coverage because of its source (*i.e.*, use of medical marijuana) may violate HIPAA if the health plan would otherwise cover the treatment for the underlying medical condition (*e.g.*, breast cancer).

Discrimination

A health plan and issuer cannot discriminate against a patient or physician that participates in the CUMMA. A patient that receives an authorization to use marijuana must have initial and continued access to healthcare. The ACA requires access to healthcare regardless of the patient's medical history. If a health plan prohibits entry of the participant into the plan due to the use of marijuana, the plan is considering the patient's health status, smoking marijuana, to deny health coverage.[16] In addition, a health plan cannot rescind or prevent renewal of coverage except in certain instances (*e.g.*, non-payment of premium, fraud, or misrepresentation). Similarly, a health plan cannot discriminate against a medical provider by not paying or otherwise permitting participation in the health plan's network due to participation in the CUMMA. The CUMMA requires a treating physician to be licensed and in good standing to practice medicine in the state of New Jersey and to be registered with the state to authorize medical use of marijuana.[17] The ACA prohibits refusal to cover medical care by a particular healthcare provider acting within the scope of the provider's license or certification under applicable state law.[18] Thus, a physician licensed in New Jersey cannot be treated adversely for participating in the CUMMA.

Tax Provisions

Similar to the disparate treatment of marijuana by federal law governing health plans, marijuana is also treated differently by the tax code. The cost of physician visits to establish a *bona fide* physician-patient relationship is excludable from income for tax purposes. However, the costs of marijuana and a stand-alone authorization visit are not excludable from income. The IRC excludes from taxation medical care, which includes amounts paid for the diagnosis, cure, mitigation, treatment or prevention of disease and excludes cosmetic or experimental treatment.[19] For patients the exclusion applies to any employer-provided healthcare, including flexible spending arrangements (FSA) and health reimbursement arrangements (HRAs) or out-of-pocket costs paid directly to the physician or reimbursed through a health savings account (HSA). Employers that reimburse for the cost of marijuana cannot deduct the expense under the IRC. Similarly, patients who pay for the cost of marijuana cannot deduct the expenses on personal income tax returns.

As more states continue to legalize marijuana, legislation at the federal level is important to effectuate uniformity. To this end, two congressional bills have been introduced to ease the research guidelines applicable to marijuana: the Marijuana Effective Drug Studies Act of 2018 (MEDS Act)[20] and the Medical Cannabis Research Act of 2018.[21] These bills may be the first step to ultimately permit the approval of marijuana as a drug by the FDA and establish its uniform treatment in healthcare. ⚖

Endnotes

1. N.J. Stat. Ann. § 24:6I-1 *et seq.* (New Jersey Statutes (2018 Edition)).
2. *Ibid.* at § 24:6I-3(5)(e).
3. *Ibid.* at § 24:6I-3.
4. Per N.J. Stat. Ann. § 24:6I-3, debilitating conditions include: seizure disorder, including epilepsy; intractable skeletal muscular spasticity; post-traumatic stress disorder; or glaucoma; severe nausea or vomiting, cachexia, or wasting syndrome; positive status for human immunodeficiency virus; acquired immune deficiency syndrome; or cancer, amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy, or inflammatory bowel disease, including Crohn's disease; and terminal illness. Furthermore, per the March 23 report following the Jan. 2018 executive order by Governor Phil Murphy, the following conditions have been added: musculoskeletal disorders, migraine, anxiety, chronic pain of visceral origin and Tourette's syndrome. These additional conditions will be covered effective March 27, 2018. *see* NJ Health, Executive Order 6 Report (March 23, 2018), http://www.state.nj.us/health/medicalmarijuana/documents/EO6Report_Final.pdf.
5. Public Health Service Act § 2713, 42 U.S.C. § 300gg-6. (2010).
6. *Ibid.* and *see* USPSTF A and B Recommendations, https://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/ (last visited June 1, 2018).
7. Experimental or investigational limits are permissible under the Affordable Care Act. *See* 29 C.F.R. § 2590.702(a).
8. *See* State Legislation on Marijuana. https://www.fda.gov/newsevents/publichealthfocus/ucm421163.htm (last visited May 31, 2018).
9. The CSA classifies marijuana as a Schedule I drug. *See* 21 U.S.C. §801, *et seq.*
10. On June 25, 2018, the FDA approved Epidiolex an oral solution for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome for children ages two and older. Epidiolex contains a drug substance derived from marijuana, cannabidiol, which does not cause intoxication. The approval from the FDA is based on clinical and non-clinical review conducted by GW Research, Ltd. While the FDA has approved the drug, it cannot yet be sold to consumers until the Drug Enforcement Administration (DEA) reclas-

sifies the drug—removes the Schedule I classification under the CSA. *See* "FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, sever forms of epilepsy," https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm (last visited July 13, 2018).

11. Is the Product a Medical Device? https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm (last visited May 31, 2018).
12. 26 U.S.C. § 213(d)(1).
13. *See* Publication 502, Medical and Dental Expenses, which provides, in pertinent part, "You cannot include in medical expenses amounts you pay for controlled substances (such as marijuana…) that are not legal under federal law, even if such substances are legalized by state law." Publication 502 (2017), Medical and Dental Expenses, https://www.irs.gov/publications/p502 (last visited May 31, 2018).
14. 29 C.F.R. § 2590.702(b)(2)(iii).
15. *Ibid.* and *see* Part 7 Compliance Checklist, DOL, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/publications/compliance-assistance-guide-appendix-a.pdf (last visited May 31, 2018).
16. 29 C.F.R. § 2509.701-2.
17. N.J. Stat. Ann. § 2C:35-2 (New Jersey Statutes (2018 Edition)).
18. P.H.S.A. § 2706(a), 42 U.S.C. § 300gg-5 (2010); *see* Affordable Care Act Implementation FAQs, Set 15, https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xv.pdf (last visited May 31, 2018).
19. *See* 26 U.S.C. §§ 105, 106 and 213.
20. The Marijuana Effective Drug Studies Act of 2018 (MEDS Act), https://www.congress.gov/bill/115th-congress/house-bill/4825 (last visited May 31, 2018).
21. The Medical Cannabis Research Act of 2018, https://www.congress.gov/bill/115th-congress/house-bill/5634 (last visited May 31, 2018).