AIMED ALLIANCE

December 1, 2020

Via Electronic Communication

John J. Burzichelli
Appropriations Chair
New Jersey Legislature
asmburzichelli@njleg.org

Joann Downey
Assembly Human Services Committee Chair
New Jersey Legislature
aswdowney@njleg.org

Herb Conaway
Assembly Health Committee Chair
New Jersey Legislature
asmburzichelli@njleg.org

Re: Opposition to NJ A. 1708

Dear Assembly Members Burzichelli, Conway, and Downey:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to express concern about NJ A. 1708, which would require reimbursement for medical marijuana products that have not received approval from the U.S. Food and Drug Administration (FDA). As you know, on October 26, the NJ Assembly Appropriations Committee introduced an amendment to NJ A. 1708 that expands the marijuana coverage mandate to various health plans. We are concerned that this bill (1) conflicts with current state and federal law, and therefore, is invalid, and (2) poses health and safety risks to New Jersey residents because it promotes the use of illicit substances to treat medical conditions, despite a lack of evidence of safety and efficacy of such substances.

A. Conflicts with State Law

NJ A. 1708's requirement that the Medicaid program and private health plans provide coverage of marijuana is in direct conflict with current state law. N.J. Stat. Ann. § 24:6I-14 currently states that "[n]othing in this act shall be construed to require a government medical assistance program [i.e., Medicaid] or private health insurer to reimburse a person for costs associated with the medical use of marijuana. . . ."[1] NJ A. 1708 does not propose to revise this language. However, the newly added Section 5 of NJ A. 1708 states that "[a] carrier that offers a health benefits plan in this State shall provide coverage for costs associated with the medical use of cannabis provided that the covered person is a qualifying patient authorized for the medical use of cannabis." Carriers is defined as an "insurance company, health service corporation, hospital service corporation, medical service corporation, or health maintenance organization authorized to issue health benefits plans in this State or any entity contracted to administer health benefits in connection with the State Health Benefits Program (SHBP), or School Employees' Health Benefits Program." Therefore, the language proposed in Section 5 conflicts with New Jersey's current law, which prohibits the state from requiring the Medicaid program or private health insurers to

[1] NJ P.L.2009, c.307, Section 16 (C.24:6I-14)

reimburse for medical use of marijuana. To avoid this conflict, Section 5 of the bill should be struck down in its entirety.

B. Health and Safety Risks

Aimed Alliance is concerned that marijuana products used to treat medical conditions that have not been evaluated by the FDA for safety and efficacy pose health and safety risks for patients. As noted by the FDA, non-FDA-approved marijuana products "can have unpredictable and unintended consequences, including serious safety risks" and that "there has been no FDA review of data from rigorous clinical trials to support that … unapproved products are safe and efficacious . . . ."[2] For example, the American Heart Association recently noted that marijuana use can result in an increased risk of heart attacks and strokes as well as impaired heart functioning.[3] Additionally, in 2019, the U.S. Surgeon General released a health advisory, which warned the public of the risks of cannabis use among pregnant women and adolescents.[4]

Given that non-FDA-approved marijuana products do not have to go through the rigorous safety and efficacy protocols or meet standards for quality, purity, and dosage, many of these products are often adulterated with harmful substances, including high levels of THC, heavy metals, toxins, and mold. The FDA demonstrated this in its July 2020 study, which found that nearly 50 percent of the tested CBD products had THC levels above the Limit of Quantification.[5] Other studies have found synthetic, psychoactive adulterants, such as "spice" / "K2," and other dangerous illicit substances in one third of the tested cannabidiol (CBD) vape oils.[6] And one study from 2019 showed that 70 percent of the CBD products tested were "highly contaminated" with heavy metals, such as lead and arsenic, herbicides, and pesticides.[7]

Despite serious health concerns associated with cannabis use, robust studies assessing the benefits of cannabis products versus the short- and long-term risks have not been performed. As a result, consumers have experienced harmful adverse events. The U.S. Army, for example, issued a warning in 2018 after approximately 60 people over the course of a few months presented with symptoms such as headaches, nausea, vomiting, disorientation, agitation, and seizures due to adulterated CBD products at two bases in North Carolina.[8] A few months later, North Carolina

---

[2] *FDA and Cannabis: Research and Drug Approval Process*, FDA, https://www.fda.gov/news-events/public-health-focus/fda-and-cannabis-research-and-drug-approval-process (last updated Oct. 1, 2020).
[3] *Marijuana May Hurt Heart, More Research Needed, Report Finds*, Am. Heart Ass'n (Aug. 5, 2020), https://www.heart.org/en/news/2020/08/05/heart-risks-of-marijuana-use-need-more-research.
[4] *Surgeon General Releases Advisory on Marijuana's Damaging Effects on the Developing Brain*, HHS (Aug. 29, 2019), https://www.hhs.gov/about/news/2019/08/29/surgeon-general-releases-advisory-marijuana-damaging-effects.html.
[5] *Sampling Study of the Current Cannabidiol Marketplace to Determine the Extent that Products are Mislabeled or Adulterated*, FDA (2020), https://aimedalliance.org/wp-content/uploads/2020/07/CBD-Marketplace-Sampling_RTC_FY20_Final.pdf.
[6] Holbrook Mohr, *Some CBD Vapes Contain Street Drug Instead of the Real Thing*, AP NEWS (Sept. 16, 2019), https://apnews.com/article/7b452f4af90b4620ab0ff0eb2cca62cc.
[7] Lisa Fletcher, *The Risk of Contaminants and False Labeling in the Exploding CBD Industry*, WJLA (May 15, 2019), https://wjla.com/features/7-on-your-side/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry.
[8] Mark Hay, *Everything We Know About the Health Risks of Vaping CBD,* VICE (Aug. 27, 2018), https://tonic.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd; *Public Health Alert: Health Effects of Vape Oils Containing Unknown Substances*, ARMY PUB. HEALTH CTR. (Aug. 31, 2020), https://phc.amedd.army.mil/topics/healthyliving/tfl/Pages/VapeOils.aspx.

health officials issued their own warning after approximately 30 people presented in the emergency departments with hallucinations, loss of consciousness, and heart irregularities linked to adulterated CBD.[9] Similarly, Nevada recently issued a public health and safety advisory because it identified several non-FDA-approved cannabis products contained yeast, mold, bacteria, and fungi, which are particularly dangerous to consumers with suppressed immune systems.[10] These products had been sold legally at 30 dispensaries within the state.[11] Likewise, a Hawaii Department of Health whistleblower – a board-certified cannabis physician in the state – identified lack of proper controls over Hawaii's marijuana dispensaries.[12] The physician noted that at least one third of his patients reported safety concerns with vaping cartridges containing THC oils purchased from state-regulated shops.[13] Tests of the oils showed dangerously high concentrations of ethanoyl (e.g., 10 times the ethanol allowed in Colorado), which can cause eye, lung, nose, and throat irritation among other harms.[14]

C. Conflict with Federal Law

This bill would force insurers to choose between violating state or federal law. Marijuana is a schedule I substance under the federal Controlled Substances Act (CSA), which means that it has no currently accepted medical use and has a high potential for abuse.[15] The CSA makes it a crime to "knowingly or intentionally . . . possess" and to "knowingly or intentionally . . . manufacture, distribute, or dispense, or possess with the intent to manufacture, distribute, or dispense" a schedule I substance.[16] Courts have found that state laws mandating coverage of illicit substances directly conflict with the CSA and may require health plans or employers to aid and abet in the violation of the CSA.[17]

Additionally, non-FDA-approved cannabis products, including CBD products, are often marketed for therapeutic purposes in violation of the Food Drug and Cosmetic Act (FDCA).[18] The FDCA only permits manufacturers of FDA-approved drugs to make therapeutic claims about their products.[19] Currently, the FDA has only approved four prescription drugs containing cannabis –

---

[9] Mark Hay, *supra* note 8.
[10] *Public Health and Safety Advisory 2020-05*, STATE OF NEV., DEP'T OF TAXATION, (Feb. 21, 2020), https://tax.nv.gov/uploadedFiles/tax.nv.gov/Content/MME/Public%20Health%20and%20Safety%20Advisory%20Cannex%202020-05%20(006).pdf; Jenny Kane, *Another Marijuana Health Advisory Issued for Products Sold at 30 Dispensaries in Nevada*, RENO GAZETTE JOURNAL (Feb. 24, 2020), https://www.rgj.com/story/news/marijuana/2020/02/24/nevada-dispensaries-sold-tainted-marijuana-pot-health-advisory-issued/4857545002/.
[11] *Id.*
[12] Allyson Blair, *State-Regulated Marijuana Vape Cartridges Aren't Safe, Doctor and Whistleblower Say*, HAWAII NEWS NOW (June 3, 2020), https://www.hawaiinewsnow.com/2020/06/03/state-regulated-marijuana-vape-cartridges-arent-safe-doctor-whistleblower-say/.
[13] *Id.*
[14] *Id.*
[15] 21 U.S.C. § 812(b)(1).
[16] 21 U.S.C. § 841(a)(1).
[17] Bourgoin v. Twin Rivers Paper Co., 187 A.3d 10 (Me. Sup. Jud. Ct. 2018); Slip Opinion, *In re* Daniel Wright, SCR-12873 at *1-2 (Mass. Oct. 27, 2020).
[18] 21 U.S.C. §§ 321(g)(1), 331, 355; *see, e.g.*, *FDA Warns 15 Companies for Illegal Selling Various Products Containing Cannabidiol as Agency Details Safety Concerns*, FDA (Nov. 25, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details.
[19] 21 U.S.C. §§ 321(g)(1), 331, 355.

one cannabis-derived and three cannabis-related drug.[20] These products are indicated for the treatment of seizures associated with rare and severe forms of epilepsy, anorexia associated with weight loss in patients with AIDS, and nausea and vomiting associated with cancer chemotherapy.[21] Yet, manufacturers of non-FDA-approved cannabis products have made numerous unsubstantiated claims, including that their products can prevent, diagnose, mitigate, treat, or cure several medical conditions, including Alzheimer's Disease, autism, cancer, diabetes, heart disease, kidney disease, liver disease, opioid use disorder, Parkinson's Disease, and most recently, COVID-19.[22] Additionally, manufacturers of non-FDA-approved cannabis products have marketed their products as dietary supplements or food.[23] Yet, the FDA has clearly stated that it is illegal to market such products by adding it to a food or labeling it as a dietary supplement.[24] Given that these foods and supplements that contain cannabis have not gone through the FDA's rigorous safety and efficacy process, they are illegal under federal law.[25]

As a result of these conflicts, health insurers could face criminal prosecution or civil asset forfeiture if they choose to comply with the state mandate. While the bill states that carriers are not required to cover cannabis upon intervention by the federal government to enforce the CSA, at that point, it may be too late for health insurers to avoid penalties.

In conclusion, to protect patient health and safety and to avoid conflicts with current state and federal law, we encourage the New Jersey Legislature not to pass NJ A 1708. Please contact us at policy@aimedalliance.org if you have any questions.

Sincerely,

Stacey L. Worthy
Counsel

Cc:

John F. McKeon, Assembly Financial Institutions and Insurance Committee Chair
Eliana Pintor Marin, Assembly Budget Chair

---

[20] *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, FDA (Oct. 1, 2020), https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill ([hereinafter "FDA REGULATION OF CBD"]).
[21] *Id.*
[22] *Warning Letters and Test Results for Cannabidiol-Related Products*, FDA (Aug. 20, 2020), https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products.
[23] *FDA Regulation of Dietary Supplement & Conventional Food Products Containing Cannabis and Cannabis-Derived Compounds*, FDA, https://www.fda.gov/media/131878/download (last visited Nov. 3, 2020).
[24] *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-Derived Compounds, Including CBD*, FDA, https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis#:~:text=The%20FDA%20has%20approved%20only,it%20as%20a%20dietary%20supplement (last updated Mar. 5, 2020). But note that the FDA considers certain foods containing hemp and hemp seed-derived food ingredients to be "generally recognized as safe" or GRAS. *FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food*, FDA, (Dec. 20, 2018), https://www.fda.gov/food/cfsan-constituent-updates/fda-responds-three-gras-notices-hemp-seed-derived-ingredients-use-human-food.
[25] 21 U.S.C. §§ 811(c)(17), 812(c); 21 C.F.R. §§ 1308.11(d)(23), (58); 21 U.S.C. §§ 352(f)(1), (f)(2); *Id.* at § 355(a); FDA REGULATION OF CBD, *supra* note 20.

Joseph F. Vitale, Senate Health, Human Services, and Senior Citizens Committee Chair
Nellie Pou, Senate Commerce Committee Chair
Paul A. Sarlo, Senate Budget and Appropriations Committee Chair
Justin Braz, Legislative Director
George Helmy, Chief of Staff
Jennifer Keyes Maloney, Assistant Treasurer
Zakiyah Ellis Smith, Advisor
Kate McDonnell, Counsel
Shabnam Salih, Policy
Jeff Brown, Assistant Commissioner Medicinal Marijuana
Judy Persichilli, Commissioner of Health