Comment on Proposed Regulation

CALIFORNIA CODE OF REGULATIONS TITLE 16, DIVISION 42
BUREAU OF MEDICAL CANNABIS REGULATION
November 16, 2017

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November 28, 2017

BCC'S PROPOSED DAILY LIMIT IS TOO PERMISSIVE AND WILL IMPOSE UNNECESSARY RISKS ON THE HEALTH OF CALIFORNIANS

Legalization of cannabis for medical and, more recently, recreational use in California and other states represents a sea change in the regulatory approach to the substance, despite its continued illegality under federal law. ***The creation and government endorsement of a legal cannabis industry that will span both medical and recreational use presents risks that the new industry will use modern product design, advertising and promotion seek to drive up demand, exploit abusive use to increase profit, and exert powerful influence over the regulatory environment.***

Protecting the public health requires that both medical and recreational cannabis markets be well controlled and designed to prevent the emergence of a powerful industry that resembles the tobacco or alcohol industries. Indeed, in the 1970s the tobacco industry actively considered entering the anticipated legal marijuana market.[1] The tobacco and alcohol industries have a long well-documented history of using their economic and political power to engage in predatory marketing practices (such as marketing to youth and encouraging high consumption of their products) with the attendant damage to the health of Californians. These activities include marketing to adolescents (although the industries strenuously deny doing so) and encouraging

[1] Barry RA, Hiilamo H, Glantz SA. Waiting for the Opportune Moment: The Tobacco Industry and Marijuana Legalization. *Milbank Q* 2014;92(2): 207-242. doi: 10.1111/1468-0009.12055

high consumption of their products, particularly among vulnerable populations, as well as actions to limit advertising restrictions, to limit on public use, to limit locations of sales outlets, and to keep taxes low. Recognizing that heavy alcohol users represent a major market strata, the alcohol industry has targeted heavy consumers as a reliable source of profits. It is important that the Bureau be cognizant of these risks and develop its regulations to minimize the chance that the burgeoning legal cannabis industry revisits upon the public the same pernicious tactics historically used by the tobacco and alcohol industries that continue to be so damaging to public health.

Unless the State of California clearly adopts a public health framework for regulating this new legal market, [2] ***normal profit-maximizing behavior by business is likely to impose health costs on the people of California similar to those imposed by the tobacco and alcohol industries, including using their political power to oppose effective regulatory, tax, and public education policies that would reduce consumption and profits.***

Research into potential harms and benefits of medical cannabis use is still developing, but existing evidence of harm is sufficient to support a precautionary approach to regulation. Among other risks, marijuana and tobacco smoke share similar toxicity profiles,[3] and the State of California has listed cannabis smoke on the Proposition 65 list of substances known to cause cancer.[4,5] The 2016 National Academies of Sciences, Engineering and Medicine report *The Health Effects of Cannabis and Cannabinoids* concluded that cannabis smoking was associated with worse respiratory symptoms and more frequent chronic bronchitis episodes, as well as moderate evidence of other respiratory effects.[6] Even secondhand exposure to marijuana smoke has negative cardiovascular effects; a recent study in rats found that one minute of exposure impaired normal functioning of arteries (endothelial function) for at least ninety minutes.[7] Changes in endothelial function are associated with development of heart disease and triggering heart attacks.[8,9]

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[2] Barry RA, Glantz SA. A Public Health Framework for legalized Retail marijuana Based on the US Experience: Avoiding a New Tobacco Industry. *PLoS Med* 2016;13(9): e1002131. doi: 10.1371/journal.pmed.1002131

[3] Moir D, Rickerrt WS, Levasseur G, Larose Y, Maertens R, White P, et al. (2008). A Comparison of Mainstream and Sidestream Marijuana and Tobacco Cigarette Smoke Produced under Two Machine Smoking Conditions. *Chem Res Toxicol 21*: 494–502. pmid:18062674

[4] 27 CCR § 25603.3.

[5] Reproductive and Cancer Hazard Assessment Branch Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Evidence on the Carcinogenicity of Marijuana Smoke (2009).

[6] National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research.* Washington, DC: The National Academies Press. doi: 10.17226/24625.

[7] Wang X, Derakhshandeh MS, Liu J, et al. One Minute of Marijuana Secondhand Smoke Exposure Substantially Impairs Vascular Endothelial Function. *J Am Heart Assoc* 2016;5:e003858. https://doi.org/10.1161/JAHA.116.003858.

[8] Widlandky ME, Gokce N, Keaney JF Jr, Via JA. The clinical implications of endothelial dysfunction. *J Am Coll Cardiol* 2003; 42(7): 1149-60.

[9] Yeboah J, Folsom AR, Burke GL, et al. Predictive Value of Brachial Flow-Mediated Dilation for Incident Cardiovascular Events in a Population-Based Study: The Multi-Ethnic Study of Atherosclerosis. *Circulation* 2009; 120(6): 502-509. doi: 10.1161/CIRCULATIONAHA.109.864801.

Vaporized forms of cannabis may reduce some cancer risks associated specifically with combustion, but likely still present risks like those of e-cigarettes and similar products, including inhalation of ultrafine particles and various chemical additives (e.g., diacetyl, propylene glycol, flavoring compounds).[10,11,12] Inhalation of ultrafine particles causes cardiovascular and pulmonary disease, including triggering heart attacks and asthma attacks.[13,14] Use of high-potency cannabis concentrates such as butane hash oil may increase risks for dependence, tolerance, and withdrawal among users.[15] Cannabis consumption has also been associated with altered or decreased brain function among adolescents,[16] cyclic vomiting syndrome,[17] and manifestation of psychotic disorders.[18]

A change made from the draft regulations released earlier this year protects the public health and should be maintained as now proposed:

- Removal of the carve-out found in former medical cannabis draft regulation § 5008(c) that excepted local law enforcement from conflicts of interest provisions applicable to other state employees involved in enforcement of the MAUCRSA.

There are, however, three problematic areas in the proposed regulations that still need to be revised or strengthened:

- The eight ounce daily limit, as proposed in § 5409(b)(1) is too high
- The absence of a robust unannounced inspection routine or procedure
- The absence of an explicit requirement for delivery drivers to verify age and identity of a medical cannabis delivery patient

[10] Grana R, Benowitz, N, Glantz SA. E-Cigarettes: A Scientific Review. *Circulation* 2014; 129(19): 1972-1986. doi: 10.1161/CIRCULATIONAHA.114.007667.
[11] Chun LF, Moazed F, Calfee CS, Matthay MA, Gotts JE. Pulmonary Toxicity of E-cigarettes. *Am J Physiol Lung Cel Mol Physiol* 2017 May 18:ajplung.00071.2017. doi: 10.1152/ajplung.00071.2017. [Epub ahead of print].
[12] Canistro D, Vivarelli F, Cirillo S, et al. E-cigarettes induce toxicological effects that can raise the cancer risk. *Sci Rep* 2017; 7: 2028. doi: 10.1038/s41598-017-02317-8.
[13] Pope CA 3rd, Burnett RT, Krewski D, et al. Cardiovascular mortality and exposure to airborne fine particulate matter and cigarette smoke: Shape of the exposure-response relationship. *Circulation* 2009; 120(11): 941-8 doi: 10.1161/CIRCULATIONAHA.109.857888.
[14] Talal A, Pena I, Temesgen N, Glantz SA. 2017. Electronic cigarette use and myocardial infarction: A national cross-sectional study in the United States. *(Submitted for publication)*
[15] Loflin M, Earleywine M. A new method of cannabis ingestion: The dangers of dabs? *Addictive Behav* 2014; 39(10): 1430-1433. https://doi.org/10.1016/j.addbeh.2014.05.013.
[16] Lorenzetti V, Alonso-Lana S, Youssef GJ, Verdejo-Garcia A, Suo C, Cousijn J, Takagi M, Yücel M, Solowij N. Adolescent Cannabis Use: What is the Evidence for Functional Brain Alteration? Curr Pharm Des. 2016; 22(42): 6353-6365.
[17] Blumentrath CG, Dohrmann B, Ewald N. Cannabinoid hyperemesis and the cyclic vomiting syndrome in adults: recognition, diagnosis, acute and long-term treatment. Ger Med Sci. 2017; 15:Doc06
[18] National Academies of Sciences, Engineering, and Medicine. 2017. *The health effects of cannabis and cannabinoids: The current state of evidence and recommendations for research.* Washington, DC: The National Academies Press. doi: 10.17226/24625.

The explicit addition of local law enforcement to the list of persons prohibited from holding licenses (§5005(b)) protects public health and is an appropriate revision from the former exemption to the prohibition found in the withdrawn medical cannabis draft regulations.

The general prohibitions against California state employees involved in enforcement of the cannabis code from holding medical cannabis licenses during the term of their employment in §5005 are appropriate because they will deter regulatory capture, avoid conflicts of interest, and deter corruption. ***The inclusion of local law enforcement to the categories of state and government personnel precluded from holding a license in the cannabis trade is appropriate to avoid the intrinsic conflict of interest that would exist if local law-enforcement officials had been allowed to exert market influence both as a licensee and as a law enforcement officer imbued with the discretion to enforce drug interdiction laws.***

Indeed, the Bureau, in it's Initial Statement of Reasons accompanying the withdrawn medical cannabis draft regulations, recognized the value of avoiding conflicts of interest and the appearance of impropriety as justification for the general prohibition against entering into licensure by state-level employees involved in enforcement of the MCRSA (Initial Statement of Reasons, pg. 19). The withdrawn draft regulation's allowance for local law enforcement to enter into medical cannabis licensure in a county other than that of their employment was inconsistent with the (appropriate) reasoning in the rule as applied to state officials, and, at worst, gave the appearance of lobbying or special interest influence. Moreover, the withdrawn draft exception could have engendered corruption on the part of other law enforcement officers and other government agents familiar with the police officer licensee, as they may have been incentivized to privilege the license holder or applicant to the detriment of other license holders or applicants.

Faith in the regulatory system is necessary to move the cannabis trade from the illicit market to the licit market. The Bureau's §5005 addition of local law enforcement to the category of persons prohibited from engaging in cannabis licensure in California is necessary to uphold public faith in the agency's credibility. ***We laud the Bureau for recognizing and removing the conflict of interest from the draft emergency regulations.***

The 8 ounce daily sale limit is too permissive and might contribute to diversion (§ 5409)

We agree with the Bureau in the need to impose a limit on the amount of cannabis that may be dispensed or sold to a patient to deter over-use, dependency, and dispensation leading to diversion of the product. **However, the eight (8) ounce daily limit proposed in § 5409 of the draft regulations is excessive**, may contribute to diversion of the product to illegal markets, and may attract crime to patients possessing that amount of product.

In addition, as contemplated in the emergency draft regulations, a product containing cannabis, including, but not limited to, concentrates and extractions, intended to be sold for use by medical- and adult use-cannabis consumers in California. ***The proposed regulation does not account for the fact that the concentration of THC and other active ingredients varies widely in these different forms of cannabis products; it should.***

At 2 grams per joint, eight ounces of dried flower is equivalent to about 113 joints.[19] To demonstrate the absurdity of this daily sale limit, a patient would have to smoke 4.7 joints per hour for twenty-four hours in order to consume eight ounces in a day. At this rate, and given the negative health effects of consuming that much cannabis smoke, a patient requiring higher dosages of medical cannabis for treatment would be better off consuming a concentrated form of cannabis, such as an infused chocolate bar or a tincture.

The Bureau's draft regulation § 5409 mandates a daily sale limit of eight (8) ounces to a qualifying patient. In relevant part, "(b) A licensee shall not sell more than eight ounces of medical cannabis in a single day to a single medical cannabis patient. Draft Emergency Regulations, § 5409(b)(1) (a)-(b)..

Draft regulation § 5409((a) establishes an eight (8) ounce daily sale limit for the dispensing of medical cannabis to patients. Imposition of a sale limit is justified in imposing a sale limit to: (1) prevent patients and caregivers from running afoul of the possession limit in Cal. Health & Safety Code § 11362.77(a); (2) stem the urge for a patient to purchase more than she can use and divert the excess to the grey or black markets; and (3) reduce the risk that a patient becomes a target of crime after they exit the dispensary.

The eight ounce sale limit does not differentiate between the type of cannabis goods that may be dispensed.

While the definition of cannabis and cannabis products contained in emergency draft regulation §5000(c) includes all types of cannabis products, and is inclusive of dry flower and manufactured cannabis products, §5000(c) is vague as to which category(s) of medical cannabis product the daily sale limit is referring to. ***Even assuming that a patient is withdrawing enough for a monthly supply, eight (8) ounces of dry flower per day is an excessive limit that encourages over-use driving dependency and diversion to the illicit market or to youth.***

The proposed eight ounce limit dramatically exceeds the limits in place in other states and should be substantially lowered

Our survey of 21 states and Washington, D.C. that have legalized medical cannabis (Appendix and Table of Statutes) indicates that ***California's eight (8) ounce daily sale limit of medical cannabis is the highest in the nation***. In sum,

- Two states impose daily sale limits of 1-2 ounces of medical cannabis
- Sale Limit Outliers
    - One state imposes a two ounce sale limit for a ten-day period
    - New Mexico imposes an eight ounce sale limit for a three-month period
    - Massachusetts imposes a 10 ounce sale limit for a two-month period
- Eight states impose a biweekly sale limit between 2.5-4 ounces of medical cannabis

[19] *Assumption*: Average large joint contains 2 grams of dry flower; 8 ounce daily limit X 28.3 grams/ounce = 227 grams; 227 grams/ average 2 gram joint = 113 average large joints

- Three states and Washington, D.C. imposed a monthly sale limit of 2.5 ounces of medical cannabis
- The regulatory election to tie the sale limit to the discretion of a physician is sound practice and bears resemblance to accepted practice in the medical and pharmacological fields
- Two states impose comparable eight ounce limits with dispensing terms of one month and three months

To harmonize the eight ounce possession limit and the potential needs of patients while inhibiting diversion, the Bureau should extend the daily limit term within which a patient may purchase eight ounces of medical cannabis to an extended temporal term to a standard per three months. At this point, it is difficult to recommend any term as we lack scientific evidence of dose responses to the myriad types of cannabis. ***The Bureau should conduct the needed research and submit an updated evidence-based standard for further public comment before finalizing the time period for the sales limit.***

The regulation should be revised to define the sales limit based on total THC delivered

The draft regulation and the accompanying Initial Statement of Reasons do not make clear whether the sale limit was set at an eight ounce outer limit to account for a patient electing to purchase a plurality of medical cannabis goods (*e.g.*, 2 ounces of dry flower, a cookie weighing 2 ounces, a bottle of tincture or topical totaling 4 ounces). ***All these products have different amounts of THC per ounce of finished product.*** Given that the eight ounce limit as contemplated in the Compassionate Use Act refers only to dry flower, the need for the Bureau to more clearly define a limit per category of medical cannabis goods is apparent.

In traditional medical settings, a physician would have dose response information to rely upon when prescribing a medicine to patient, and could, subsequently titrate the dosage based upon feedback from the patient during future consultation. Barring adoption of the preceding recommendations, ***the Bureau should benchmark the sale limit against a physician's recommendation issued in response to patient feedback.***

Washington state's statute provides an example that delineates between sale limits for particular categories of medical cannabis goods:

> the qualifying patient or designated provider may purchase or obtain at a retail outlet holding a medical marijuana endorsement a combination of the following: *Forty-eight ounces of marijuana-infused product in solid form; three ounces of useable marijuana; two hundred sixteen ounces of marijuana-infused product in liquid form; or twenty-one grams of marijuana concentrates*." Wash. Rev. Code Ann. § 69.51A.210(1) (West), [emphasis added].

The Washington state model language demonstrates that other state policymakers have recognized the need to clearly define limits for each category of cannabis good, which is an implicit recognition of the fact that different cannabis products deliver different amounts of THC and other active components.

The Bureau should hold issuance of a sales limit regulation in abeyance until it has had the opportunity to inform its rulemaking process with research into the dose response of medical cannabis goods. The Bureau should re-issue the sale limit recommendation based upon reasoned dose response research, and resubmit the proposed recommendation for Public Comment at a later date.

The Excessive Eight Ounce Sale Limit May Attract Robberies of Patients, Not Deter Them

Finally, as the Initial Statement of Reasons recognizes, a patient possessing an excessive amount of medical cannabis may attract robberies. However, the proposal of an eight ounce sale limit is inconsistent with this stated objective, as a criminal has greater incentive to rob a patient carrying such an excessive amount of cannabis.

For the foregoing reasons, the eight ounce medical cannabis possession limit is excessive. Instead, the Bureau should defer final rulemaking procedures on the sale limit until they have developed a sale limit based upon research into proper dosage recommendations to be resubmitted for public comment at a later date.

The regulation should explicitly establish a program of unannounced compliance inspections on a routine and frequent basis (§5800)

The Bureau has outlined its general authority to inspect dispensaries under the proposed regulations.[20] In addition, public health best practices from alcohol and tobacco control indicate that a system of unannounced compliance checks is needed to promote effective adherence to sales restrictions.[21,22,23,24,25] (California has been particularly successful in reducing youth sales using unannounced compliance checks through the STAKE Act.[26]) While there is no minimum age limit set for access to medical cannabis, restrictions on sales to individuals without a valid

[20] Bureau of Cannabis Control Proposed Text of Regulations §5800
[21] Interagency Coordinating Committee for the Prevention of Underage Drinking (ICCPUD) (2015) Annual Report to Congress on the Prevention and Reduction of Underage Drinking. Rockville, MD: Substance Abuse and Mental Health Services Administration (SAMHSA).
[22] U.S. Surgeon General (2007) The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking. Rockville, MD: Office of the Surgeon General.
[23] Office of the Surgeon General (2016) Facing Addiction in America: The Surgeon General's Report on Alcohol, Drugs, and Health. Washington, DC: US Dept of Health and Human Services.
[24] U.S. Department of Health and Human Services (2012) Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
[25] U.S. Department of Health and Human Services (2014) The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health.
[26] Landrine H, Klonoff EA, Reina-Patton A. Minors' access to tobacco before and after the California STAKE Act. *Tobacco Control* 2000;9:ii15-i17.

Medical Marijuana Recommendation presents an analogous concern and justifies a similar enforcement approach to prevent unauthorized access and product diversion.

California recently advanced its efforts to eliminate youth tobacco use by raising the minimum age to purchase or consume tobacco to 21.[27] Recreational cannabis under the recently passed Medicinal and Adult Use Cannabis Regulation and Safety Act will similarly be restricted to those over 21.[28] While there is no minimum age for medical cannabis use under current California law, robust enforcement of proper identification verification procedures is essential to reduce or eliminate efforts to misuse or abuse the medical cannabis program by those under the lawful age for non-medical cannabis consumption and those under the lawful age for tobacco consumption who may seek to substitute cannabis for tobacco. A properly regulated system for medical cannabis sales must not undo hard-fought gains in tobacco control through lack of enforcement. ***Best practices from alcohol and tobacco control indicate that unannounced compliance checks are a critical component of ensuring that retailers conform to sales regulations that protect public health.***

The regulations for delivery (§5414-§5421) should explicitly include requirement for the driver to verify the identity of the cannabis consumer

The proposed draft delivery regulations in §5414-5421 do not contain an explicit requirement for delivery drivers to verify the age and identity of the recipient who has purchased the cannabis using a delivery platform. Though §5414(c) incorporates, by reference, the age verification requirement applicable to brick-and-mortar retail license types (§5402(a)-(b)), the Bureau should explicitly clarify this duty through the addition of a clause in the applicable sections pertaining to delivery. ***Given that the Bureau recognizes the obligation for delivery persons to verify age and identity pursuant to §5402, the Bureau should include an additional provision explicitly requiring delivery persons to check the identification and age of the cannabis recipient to ensure compliance and dissuade diversion to youth or illicit markets.***

Conclusion

The BCC's proposed regulations are an important step in the process of bringing the cannabis industry into the light and away from its status as an under-regulated industry. The Bureau's removal of the local law-enforcement carve-out found in the withdrawn medical cannabis draft regulations is appropriate, as it would have codified a glaring exception from the general prohibition against state employees holding licenses during the term of their employment that would have damaged public trust. Further, we applaud the Bureau's explicit addition of law enforcement to the persons prohibited from holding a cannabis license. However, the proposed daily eight ounce sale limit is excessive and damaging to public health in that it encourages robbery crime against patients, promotes diversion, and may drive over-consumption. To bring the regulations into parity with the sale limits in other states, the Bureau should either decrease the sale limit to two (2) ounces per day or retain the eight (8) ounces limit but increase the dispensation term from per day to per three months.

[27] S.B.x2-7, 2015-2016 Leg. (Ca. 2016).
[28] CAL. HEALTH & SAFETY CODE § 11362.1 et seq.

APPENDIX

Results of State Survey on Medical Cannabis Sale Limits

Study Population

The study population includes all states having legalized medical cannabis. Florida and Maryland were excluded from the study population for not having implemented a solidified medical cannabis regulatory scheme. Oregon was excluded for being in the midst of aligning medical and recreational cannabis regulation under a unitary regulatory scheme. West Virginia was excluded for not having assigned a 30-day possession or sale limit. Michigan and Montana were excluded for not specifying either a dispensing limit nor term. Vermont was excluded for only specifying a 2.5 ounce possession limit to be shared jointly between a patient and caregiver. We then analyzed the possession and dispensing limits of the remaining 21 states and Washington DC, including: Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Hawai'i, Illinois, Maine, Massachusetts, Minnesota, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Pennsylvania, Rhode Island, and Washington, D.C. California was excluded from the Excel workbook tabulation for being the subject of this Public Comment.

Daily Limit

Two states in the study sample impose daily limits. Alaska mandates that one ounce may be dispensed per transaction, while Colorado mandates that two ounces may be dispensed per transaction (which, in practice, is taken to be a daily limit). **The Bureau's proposed daily sale limit of eight ounces far exceeds the daily sale limits set by Alaska and Colorado.**

Two Week Sale Limit

Eight states in the sample impose a dispensation schedule mandating maximum purchase limits during a 14 or 15 day term. Arizona, Arkansas, Illinois, Maine, Nevada and Rhode Island mandate that a patient may only be dispensed 2.5 ounces in a 14 or 15 day period. Delaware specifies a dispensing limit of 3 ounces in a 14-day period. Hawai'i specifies a dispensing limit of no more than 4 ounces in a 14-day period or 8 ounces in a 30-day period. **The eight ounce daily sale limit proposed by the Bureau is especially high in comparison to other states imposing more restrictive sale limits over a greater two-week dispensation term.**

30-day or Monthly Sale Limit

Three states and Washington, D.C. impose 30-day or monthly sale limits on the sale and dispensation of medical cannabis. Connecticut and North Dakota mandate a dispensing limit of 2.5 ounces per month, while New Jersey and Washington, D.C. mandate a dispensing limit of 2 ounces per 30-day month**.** Interestingly, these monthly limits are more restrictive in the sale limit than Colorado or Alaska's daily sale limit amounts. **The Bureau's proposed daily sale**

limit of eight ounces exceeds the monthly sale limits imposed by Connecticut, North Dakota, New Jersey, and Washington, D.C. by three and four fold.

Outliers

Three states were defined as outliers in that their sale limits and dispensing terms were unique from other states, and therefore, incapable of grouping by code. Of the states with outlier dispensing limits, New Mexico allows a patient to be dispensed no more than eight ounces over a three-month period, Massachusetts allows 10 ounces over a 60-day period, and New Hampshire allows 2 ounces over a ten-day period. **California's proposed eight ounce daily sale limit far exceeds all of these states' limits and appears arbitrary and excessively permissive.**

Imposition of Sale Term Without Specified Sale Limit

Five states in the study sample impose dispensing terms, without specifying the amount of medical cannabis that may be provided. Minnesota and New York prescribe 30-day and 90-day terms, respectively, and benchmark the amount to be dispensed to the physician's recommendation. Of states specifying a dispensing term without an accompanying dispensing or sale limit, Minnesota, New York, Pennsylvania, and West Virginia allow only a 30-day supply to be dispensed, while only Ohio specifies a dispensing term without an accompanying limit. **While analysis of these states is of limited utility to the present issue due to the indefinite sale limits, we argue that tying the dispensing limit to the discretion of a physician is sounder policy and more closely tracks accepted medical and pharmacy practices.** However, there exists little scholarly research on the absorption rates, pharmacokinetics, or patients' idiosyncratic dose responses to the myriad types of medical cannabis products the draft regulations contemplate, making accurate titration by physicians a difficult task. Further, without standardized dosing for each strain or product type, the justification for leaving the dosage determination to the discretion of the physician may be attenuated. **In light of the foregoing, and barring adoption of our previous recommendations, we suggest that the Bureau impose a sale limit benchmarked against a physician's recommendation for that particular patient and ailment, not to exceed the recommended amount for a standardized term.**

Eight (8) Ounce Limit

When examining the eight ounce sale limit variable in isolation, Hawai'i and New Mexico provide a foil for the proposed eight ounce daily limit. Hawa'i allows for the dispensation of eight ounces in a 30-day period, while New Mexico mandates an eight ounce sale limit during a three-month time period, terms which anticipate a more reasonable rate of consumption than the Bureau's proposed eight ounce daily sale limit.

See **Table of Statutes** for specific statutory language and citations, *attached*.

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