ARC 3151C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 17A.3(1)"b" and 136.3(9), the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 154, "Medical Cannabidiol Act Registration Card Program," Iowa Administrative Code.

On May 12, 2017, then Governor Branstad signed 2017 Iowa Acts, House File 524, which repealed existing Iowa Code chapter 124D and enacted new Iowa Code chapter 124E, the Medical Cannabidiol Act. The legislation was effective upon enactment. House File 524 expanded the state's existing Medical Cannabidiol Act in a number of ways, including expanding the list of conditions for which a patient is eligible to receive a medical cannabidiol patient or primary caregiver registration card, establishing a Medical Cannabidiol Board, providing for licensure of medical cannabidiol manufacturers and dispensaries, establishing a fee structure for registration cards and licensure applications, and adding a new requirement for a real-time, 24/7 statewide medical cannabidiol registry management sale tracking system.

With the repeal of Iowa Code chapter 124D, there is currently no process in place through which the Department can approve medical cannabidiol registration card applications. The purpose of these amendments is to update the Department's existing administrative rules adopted under the prior Medical Cannabidiol Act to reflect the amendments made to the patient and primary caregiver registration card issuance process. Additional rules will be needed to fully implement House File 524, and those rules will be brought forward at a later date.

Any interested person may make written comments or suggestions on the proposed amendments on or before July 25, 2017. Such written comments should be directed to Randy Mayer, Bureau Chief, Bureau of HIV, STD and Hepatitis, Iowa Department of Public Health, Lucas State Office Building, 321 E. 12th Street, Des Moines, Iowa 50319-0075. Comments may be sent by e-mail to randall.mayer@idph.iowa.gov.

There will be a public hearing on August 9, 2017, from 1 to 3 p.m. in Room 517-518, Lucas State Office Building, Des Moines, Iowa. This hearing will also be accessible via conference call by dialing 1-866-685-1580 and using the pass code 515-281-5606.

Waiver provisions for these rules are located at 641—Chapter 178.

These amendments are also Adopted and Filed Emergency and are published herein as **ARC 3150C**. The content of that submission is incorporated by reference.

The Department anticipates implementation of 2017 Iowa Acts, House File 524, will cause the expenditure of state funds in excess of $100,000 per year. Anticipated costs include personnel to oversee the startup and administration of the program, technology solutions that will be necessary to adequately track registration card applicants, and postage and supplies needed to communicate with card applicants.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement 2017 Iowa Acts, House File 524.

Comment #1:

As a prospective "manufacturer" of cannabis in the State of Iowa, I wanted to briefly comment on the newly released proposed regulations.

The approach being implemented by the Board of Public Health basically serves no one.
It does not serve the patients in Iowa whom currently suffer without remedy. Those patients would be relieved to be able to obtain required cannabis extracts to help their ailments, but only being able to administer a ridiculously low level of active THC relegates the efforts by the State of Iowa to being basically useless.

Many patients at this time cross state lines into Colorado in order to obtain the concentration levels they require in either Cannabidiol oils, tinctures, extracts, and in flower form for vaporizing, smoking and eating. By cutting off the possibility for any higher percentage of THC than 3%, the State of Iowa is basically giving the patient base nothing but fluff, words and air and no "real useful medicine". Patients would continue to obtain the meds they need by current methods and thus be forced to break Federal laws. Because face it, if the medications offered are of no use ... who needs them? Who would buy them?

The debilitating medical conditions we are attempting to relieve, requires the efficacy of "whole plant options". Cannabidiol (CBD), THC, Terpenes, and a host of other compounds found within the Cannabis plant work in a myriad of ways to treat these medical conditions we are working to alleviate. Nothing short of a comprehensive program that promotes an informed and effective treatment regimen is what is required for success. I would like to add that the growing body of evidence for treating PTSD in our returning troops should be a priority and that Cannabidiol (CBD) has minimal effect on their condition as does the same treatment of our growing Opioid epidemic.

The above also eliminates most serious manufacturers who have a massive upfront investment for bringing this new industry into fruition. What manufacturer would seriously step chest high into this when the constraints are so prohibitive that all potential patients would not buy the products due to such low levels of active medicine?

Potential manufacturers would most likely suffer disastrous financial ruin in short order; much like the current 2 manufacturers in Minnesota who are hemorrhaging millions of dollars and soon to be going under.

My group is very interested in launching a "successful" business that serves a growing patient base, adds value to the economy of Iowa and offers needed solid jobs for both skilled staff and laborers. But we would never begin an enterprise which would be doomed from day one.

The writers of the new bill have not served the citizens of our great state. Instead thy have barely touched this issue with utter disregard to making this viable for anyone. The choke hold will kill this potential industry before it even starts. Colorado will then continue to be the go to supplier for Iowa patients who need the medication so much that they cross state lines and risk prison.

I hope you will share these comments which are not meant to berate those whom are designing the blueprint for cannabis in Iowa, but are instead meant to show that there is a void of necessary substance at this time.

The Cannabis industry in Minnesota is failing. Let's back up a little and design a program that will serve the needs of the patients, the ability for manufacturers to operate successfully, and the State of Iowa to reap the generous tax opportunities generated by a robust new industry.

Thank you for your time today.

Kenneth MacGregor

Comments on Proposed Amendments to

641 Iowa Administrative Code 154

"Medical Cannabidiol Act Registration Card Program"

July 25, 2017

The Medical Cannabidiol Act, 2017 Iowa Acts 451, Chapter 162 (H.F. 524), was signed into law on May 12, 2017, by Governor Terry E. Branstad.

Section 7(1) of the Act, Iowa Code § 124E.4(1) (2017), authorizes the Iowa Department of Public Health to issue a registration card to a "patient" which then provides that patient with an "affirmative defense" for the possession of cannabidiol products in Iowa. See Section 15(4)(a) of the Act, Iowa Code § 124E.11(4)(a) (2017).

Section 7(3) of the Act, Iowa Code § 124E.4(3) (2017), authorizes the Iowa Department of Public Health to issue a registration card to a "primary caregiver" which then provides that primary caregiver with an "affirmative defense" for the possession of cannabidiol products in Iowa. See Section 15(4)(b) of the Act, Iowa Code § 124E.11(4)(b) (2017).

Federal Regulations

The Iowa Medical Cannabidiol Act of 2017 does not explain how possession of cannabidiol products is consistent with existing federal regulations.

The Drug Enforcement Administration (DEA) has recently published a notice in the Federal Register clarifying that cannabidiol products are federal schedule 1 controlled substances.[1] The DEA has further clarified that cannabidiol products are federal schedule 1 controlled substances on its website.[2]

Attached to this document are two letters from the Iowa Board of Pharmacy dated May 31, 2017, and June 7, 2017, confirming that cannabidiol products are both federal and state schedule 1 controlled substances.

There are no federally approved cannabidiol products. Without an explanation in the rules the Iowa Department of Public Health is proposing, Iowa patients are left facing a potential hazard.

This document explains why the Iowa Department of Public Health must resolve any inconsistency or doubt by administrative rule.

Federal Penalties

The Federal penalties for possessing cannabidiol products are quite severe, with penalties ranging from 1 to 3 years in federal prison and fines ranging from $1,000 to $5,000.[3]

Federal Enforcement Policy

While Iowa House Speaker Linda Upmeyer has suggested that federal enforcement policy might continue to overlook state medical marijuana programs, recent statements from the United States Attorney General, Jeff Sessions, have indicated otherwise.[4]

Disabled Americans have been Negatively Impacted

Because of the consistent failure of state laws and regulations to address federal regulations appropriately, disabled Americans have been severely and negatively impacted.

The Supreme Court of Colorado recently rejected an employment discrimination claim by a severely disabled person. *Coats v. Dish Network*, 350 P.3d 849, 850 (Colorado 2015) ("an activity such as medical marijuana use that is unlawful under federal law is not a 'lawful' activity under section 24-34-402.5"); *People v. Crouse*, 388 P.3d 39, 43 (Colorado 2017) ("Consistent with our holding in *Coats*, then, we again find that conduct is 'lawful' only if it complies with both federal and state law.")

And see *Gonzales v. Raich*, 545 U.S. 1 (2015) (possession of marijuana for medical use under state program unlawful under federal classification), while noting marijuana's federal schedule 1 classification may be invalid, 545 U.S., at 28 n.37; and see *Casias v. Walmart*, 695 F.3d 428 (6th Cir. 2012) (discrimination in employment allowed against participant in state medical marijuana program); and see *James v. Costa Mesa*, 700 F.3d 394 (9th Cir. 2012) (Americans with Disabilities Act does not protect participation in state medical marijuana program).

The Iowa Medical Cannabidiol Act of 2017 gives the Iowa Department of Public Health sufficient authority to resolve this potential hazard by administrative rule. State medical marijuana programs are lawful under federal law. The federal drug act was never intended to prevent the medical use of controlled substances. The federal drug act is intended to prevent the abuse, not the authorized medical use, of controlled substances.

> As we have noted before, the CSA "repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic in illicit drugs." *Raich*, 545 U.S., at 12. In doing so, Congress sought to "conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Ibid.* It comes as little surprise, then, that we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug "'pusher'" instead of a physician. *Moore*, 423 U.S., at 143.

Gonzales v. Oregon, 546 U.S. 243, 269 (2006).

Federal Law

States do not surrender their sovereignty when they become members of the union ("united states").

> Congress may not simply "commandeer the legislative processes of the States by directly compelling them to enact and enforce a federal regulatory program." *Hodel v. Virginia Surface Mining & Reclamation Assn., Inc.*, 452 U.S. 264, 288 (1981).

New York v. United States, 505 U.S. 144, 161 (1992). Federal law does not prohibit the state from accepting the medical use of a controlled substance, and federal regulations must maintain that same balance. What seems like a paradox is a question of balance between state and federal law.

Federal drug law was written to provide flexibility in the classification of controlled substances. Marijuana is currently classified as a substance with no accepted medical use in the United States. States have a significant role in federal classification.[5]

See 21 U.S.C. § 903 (2017):

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress to occupy the field in which that provision operates, including criminal penalties, to the exclusion of any State law on the same subject matter which would otherwise be within the authority of the State, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.
>
> (Pub. L. 91–513, title II, § 708, Oct. 27, 1970, 84 Stat. 1284.)

Marijuana's placement in federal schedule 1 depends on whether the DEA's interpretation of the statutory language "currently accepted medical use in treatment in the United States" is lawful. The DEA adopted its current interpretation in 1992. A federal appellate court upheld the DEA's interpretation of that language in 1994, two years before any state had accepted the medical use of marijuana. See *Alliance for Cannabis Therapeutics v. DEA*, 15 F.3d 1131 (D.C. Cir. 1994).

Let that sink in for a moment. Marijuana's current placement in federal schedule 1 is based upon a federal administrative decision in 1992, affirmed by a federal appellate court in 1994, determining that marijuana had no accepted medical use in the United States at the time it made the decision, just two years before any state had accepted marijuana for medical use, beginning in 1996.

Initial Classification by Congress

The National Commission on Marihuana and Drug Abuse was created by the Controlled Substances Act of 1970, Public Law 91-513, to study the question of marijuana abuse in the United States. While the Controlled Substances Act was being drafted in a House committee in 1970, Assistant Secretary of Health Roger O. Egeberg had recommended that marijuana temporarily be placed in schedule I, 21 U.S.C. § 812(c), Schedule 1(c)(10) (1970), the most restrictive category of drugs, pending the Commission's report. On March 22, 1972, the Commission's chairman, Raymond P. Shafer, presented a report to Congress and the public entitled "Marihuana, A Signal of Misunderstanding," which favored ending marijuana prohibition and adopting other methods to discourage use. No action was

taken on the commission's report and marijuana has remained in federal schedule 1 since that time.

Duty to Update the Classification

DEA is required to update the classifications annually as necessary. See 21 U.S.C. § 812(a) (1970). The Attorney General of the United States, in conjunction with the Secretary of Health and Human Services, may add substances to, transfer substances between, or remove substances from the classifications. See 21 U.S.C. § 811(a) (1970). The Drug Enforcement Administration (DEA) has been delegated by the Department of Justice to perform this function for the Attorney General, in conjunction with the Food and Drug Administration which has been delegated by the Department of Health and Human Services to perform its responsibilities under the act. See 21 U.S.C. § 811(b) (1970).

Contextual Analysis

The Medical Cannabidiol Act of 2017 recognizes and accepts a medical use for the marijuana plant in the state of Iowa. Section 5(6) of the Act, Iowa Code § 124E.2(6) (2017):

> "Medical cannabidiol" means any pharmaceutical grade cannabinoid found in *the plant Cannabis sativa L. or Cannabis indica* or any other preparation thereof that has a tetrahydrocannabinol level of no more than three percent and that is delivered in a form recommended by the medical cannabidiol board, approved by the board of medicine, and adopted by the department pursuant to rule.

(emphasis added).

A federal regulation (schedule 1) says marijuana has no accepted medical use in the states. See 21 C.F.R. § 1308.11(d)(22)(2017). The outdated federal regulation has not been updated since 1994, when marijuana actually had no accepted medical use in any state. The people of Iowa have now accepted the medical use of marijuana in 2017. Iowa is a state in the union ("in the United States"). The state of Iowa is not authorizing the "abuse" of marijuana. The state of Iowa is authorizing "medical use" of marijuana.

Before marijuana became accepted for medical use in any state, federal courts considering this matter determined that Congress did not define the term "currently accepted medical use," and that accepted medical use in the United States can be solely intrastate without any federal approval for interstate marketing. The best evidence of "accepted" medical use in the United States is a state law accepting the medical use of marijuana. Accepted medical use that is solely intrastate is within the meaning of "currently accepted medical use" under existing federal law.

> *Grinspoon v. DEA*, 828 F.2d 881, 886 (1st Cir. 1987):
>
> We add, moreover, that the Administrator's clever argument conveniently omits any reference to the fact that the pertinent phrase in section 812(b)(1)(B) reads "*in the* United States," (emphasis supplied). We find this language to be further evidence that the Congress did not intend "accepted medical use in treatment in the United States" to require a finding of recognized medical use in every state or, as the Administrator contends, approval for interstate marketing of the substance.
>
> *Grinspoon v. DEA*, 828 F.2d 881, 887 (1st Cir. 1987):
>
> Unlike the CSA scheduling restrictions, the FDCA interstate marketing provisions do not apply to drugs manufactured and marketed wholly intrastate. Compare 21 U.S.C. § 801(5) with 21 U.S.C. § 321 (b), 331, 355(a). Thus, it is possible that a substance may have both an accepted medical use and safety for use under medical supervision, even though no one has deemed it necessary to seek approval for interstate marketing.

After the ruling in *Grinspoon*, the federal courts and the DEA began to address the question of how the DEA determines whether a controlled substance has accepted medical use in the United States.

> *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C. Cir. 1991):
>
> The difficulty we find in petitioners' argument is that neither the statute nor its legislative history precisely defines the term "currently accepted medical use"; therefore, we are obliged to

> defer to the Administrator's interpretation of that phrase if reasonable.

In 1992, the DEA acknowledged that Congress did not authorize the DEA to decide whether the states can or should accept the medical use of marijuana. The DEA can only acknowledge the decision "others" have made.

> *Marijuana Scheduling Petition*, DEA Docket No. 86-22, 57 Fed. Reg. 10499 (March 26, 1992) 10506:
>
> Clearly, the Controlled Substances Act does not authorize the Attorney General, nor by delegation the DEA Administrator, to make the ultimate medical and policy decision as to whether a drug should be used as medicine. Instead, he is limited to determining whether others accept a drug for medical use. Any other construction would have the effect of reading the word "accepted" out of the statutory standard.

It would be strange indeed if "others" did not include states. We are a nation of laws. State medical marijuana laws are proof beyond any doubt that marijuana has accepted medical use in the United States. Opinions don't matter; but laws do. It is not reasonable, or lawful, for the DEA to reject state laws as evidence of "accepted" medical use.

> *Gonzales v. Oregon*, 546 U.S. 243, 258 (2006):
>
> The Attorney General has rulemaking power to fulfill his duties under the CSA. The specific respects in which he is authorized to make rules, however, instruct us that he is not authorized to make a rule declaring illegitimate a medical standard for care and treatment of patients that is specifically authorized under state law.

State Law

The Iowa Medical Cannabidiol Act of 2017, H.F. 524, Section 5(6), Iowa Code § 124E.2(6) (2017), defines "medical cannabidiol" as a "pharmaceutical grade cannabinoid found the plant Cannabis." The Act specifically authorizes the cultivation and harvesting of marijuana plants to

make medical cannabidiol products. See H.F. 524, Section 9(1)(a), Iowa Code § 124E.5(1)(a) (2017).

Iowa has determined that there is an "accepted" medical use for marijuana and the federal courts have determined that state laws accepting the medical use of a controlled substance are harmonious with the federal Controlled Substances Act. The Iowa legislature hasn't included this statement of compliance with existing federal law in the Medical Cannabidiol Act. A statement of compliance needs to be included in 641 IAC 154 so that patients and their families are not left in doubt about their legal status and personal safety.

The Elephant in the Room

> "Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions – it does not, one might say, hide elephants in mouseholes." *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001).

Gonzales v. Oregon, 546 U.S. 243, 267 (2006):

H.F. 524 also fails to remove marijuana from Iowa schedule 1. Iowa schedule 1, like it's federal counterpart, says marijuana has no accepted medical use in treatment in the United States (unless the Iowa Board of Pharmacy says it does by an administrative rule). Iowa Code § 124.204(4)(m) (2017); Iowa Code § 124.203(1)(b) (2017). State law, H.F. 524, now says marijuana does have an accepted medical use in the state.

In 2010, the Iowa Board of Pharmacy, which is authorized by law to make recommendations to the legislature pursuant to Iowa Code § 124.201 (2017), recommended that marijuana be removed from Iowa schedule 1.

Attached to this document is the February of 2010 recommendation from the Iowa Board of Pharmacy, the February of 2010 press release from the Iowa Department of Public Health, and the legislation that was pre-filed in December of 2010 by the department and the board in the 84th General Assembly (2011-2012) of Iowa.

Moving forward without addressing marijuana's classification in schedule 1 can and will have tragic consequences.

The Iowa Senate bill, S.F. 506, that passed by a vote of 45-5 on April 17, 2017, in the Iowa Senate, included the Iowa Board of Pharmacy's recommendation from February 17, 2010, recommending the removal of marijuana from schedule 1. The House version did not include the board's recommendation. The House version, H.F. 524, wasn't made publicly available until 3:00 a.m. on the morning of the day after the legislature was scheduled to adjourn for the year on April 21, 2017. H.F. 524 passed in the Iowa House at 5:30 a.m. on April 22, 2017, and in the Iowa Senate at 6:30 a.m. on April 22, 2017. The House version was not carefully vetted.

Comparing Classifications

Both state and federal drugs laws reveal that we do not put plants with medical use in schedule 1.[6]

Marijuana has Medical Use in 46 States

Since 1996, four years after the DEA issued it interpretive rule in 1992, thirty states have accepted the medical use of marijuana, and another sixteen states have accepted the medical use of a marijuana extract (cannabidiol), bringing the total to 46 out of 50 states now depending on marijuana plants for medical use or for making extracts for medical use. In addition, DC, Puerto Rico, and Guam have accepted the medical use of marijuana.

See National Conference of State Legislatures, July 7, 2017, State Medical Marijuana Laws:

http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx

Conclusion

Regulations must include an explanation of compliance with existing state and federal laws. This can't be left to the imagination. Failure to address classification of marijuana in H.F. 524 leaves Iowa patients and their loved ones at risk of losing access to medical cannabidiol and facing severe federal penalties. The Iowa Department of Public Health has the authority to take corrective action by administrative rule. Each medical cannabidiol registration card must include a statement that the card immunizes the patient and/or caregiver from federal prosecution that would result from the false assumption that marijuana is lawfully classified as a schedule 1

substance. The Iowa Board of Pharmacy has the authority to fix the state classification because it has the authority to reclassify marijuana by administrative rule[7]. H.F. 524 satisfies federal requirements because it nullifies federal schedule 1 (either on its face, or as applied).

Thank you for your prompt attention to this matter.

Carl Olsen, Executive Director
Iowans for Medical Marijuana, Iowa Business No. 334412
Post Office Box 41381, Des Moines, Iowa 50311-0507
http://www.iowamedicalmarijuana.org/

[1] Federal Register

Vol.81, No. 240, Wednesday, December 14, 2016, pp. 90194-90196.

[2] DEA Clarification on Cannabidiol

https://www.deadiversion.usdoj.gov/schedules/marijuana/m_extract_7350.html

[3] Federal Penalties

21 U.S.C. § 844(a) (2017) First offense $1,000 fine — up to one year in prison
21 U.S.C. § 844(a) (2017) Second offense $2,500 fine — up to two years in prison
21 U.S.C. § 844(a) (2017) Third and subsequent offense $5,000 fine— up to three years in prison

[4] Media Reports

March 27, 2017, KGLO Radio, Mason City, Iowa, "Upmeyer says legislators working on medical marijuana issue."
June 13, 2017, The Cannabist, an edition of the Denver Post, Denver, Colorado, "Jeff Sessions has asked Congress to allow him to prosecute medical marijuana providers."
June 16, 2017, Globe Gazette, Mason City, Iowa, "Sessions wants flexibility to prosecute Iowa medical marijuana program."
June 23, 2017, Quad City Times, Davenport, Iowa, "Editorial: Jeff Sessions eyes pot crackdown on Iowa, Illinois."

[5] Federal Classifications

Schedule 1 21 U.S.C. § 812(b)(1) (2017) no medical use and high potential for abuse without consideration for physical or psychological dependence.
Schedule 2 21 U.S.C. § 812(b)(2) (2017) medical use with high potential for abuse with physical dependence and high psychological dependence.
Schedule 3 21 U.S.C. § 812(b)(3) (2017) medical use with low to moderate physical dependence and high psychological dependence.
Schedule 4 21 U.S.C. § 812(b)(4) (2017) medical use with physical dependence and psychological dependence less than schedule 3.
Schedule 5 21 U.S.C. § 812(b)(5) (2017) medical use with physical dependence and psychological dependence less than schedule 4.

[6] Classification Comparisons

Schedule 1 Iowa Code § 124.204(4)(m) (2017) Marijuana
Schedule 2 Iowa Code § 124.206(2)(a)(1) (2017) Raw Opium Iowa Code § 124.206(2)(a)(7) (2017) Codeine Iowa Code § 124.206(2)(a)(10) (2017) Hydrocodone Iowa Code § 124.206(2)(a)(13) (2017) Morphine Iowa Code § 124.206(2)(c) (2017) Opium Poppy and Poppy Straw
Schedule 3 Iowa Code § 124.208(5)(a)(1) (2017) Codeine Iowa Code § 124.208(5)(a)(2) (2017) Codeine Iowa Code § 124.208(5)(a)(3) (2017) Hydrocodone Iowa Code § 124.208(5)(a)(4) (2017) Hydrocodone Iowa Code § 124.208(5)(a)(5) (2017) Hydrocodone Iowa Code § 124.208(5)(a)(7) (2017) Opium
Schedule 5 Iowa Code § 124.212(2)(a) (2017) Codeine Iowa Code § 124.212(2)(b) (2017) Hydrocodone Iowa Code § 124.212(2)(e) (2017) Opium

[7] Iowa Board of Pharmacy

Iowa Code § 124.204 (2017)
Schedule I.
4. Hallucinogenic substances.
m. Marijuana, *except as otherwise provided by rules of the board for medicinal purposes.*

Iowa Code § 124.206 (2017)
Schedule II.
7. Hallucinogenic substances.
a. Marijuana *when used for medicinal purposes pursuant to rules of the board.*

(emphasis added). See *State v. Bonjour*, 694 N.W.2d 511 (Iowa 2005), for the history of this authority.

Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

May 31, 2017

Carl Olsen
130 E Aurora Ave
Des Moines IA 50313

RE: Petition for Agency Action

Mr. Olsen,

On May 12, 2017, you submitted a Petition for Agency Action to the board requesting the board to determine whether cannabis extracts are new substances designated as controlled substances under federal law, and to take appropriate action. The Iowa Administrative Procedure Act (Iowa Code chapter 17A) does not establish a right or a procedure for an individual to petition for agency action of this nature.

As you are aware, "[i]f any *new* substance is designated as a controlled substance under federal law and notice of the designation is given to the board, the board shall similarly designate as controlled the new substance under this chapter after the expiration of thirty days from publication in the federal register of a final order designating a new substance as a controlled substance, unless within that thirty-day period the board objects to the new designation." Iowa Code § 124.201(4) (emphasis added). The board regularly receives notices of scheduling changes from the Drug Enforcement Administration (DEA).

On December 14, 2016, the DEA published a final rule establishing a new drug code for marihuana extract. Establishment of a New Drug Code for Marihuana Extract, 81 Fed. Reg. 90,194 (December 14, 2016) (to be codified at 21 C.F.R. 1308.11(d)(58). According to the publication, the new code number will allow DEA and registered entities to track quantities of marihuana extract separately from quantities of marihuana. The DEA indicated a new drug code was needed because "[t]he United Nations Conventions on international drug control treats extracts from the cannabis plant somewhat differently than marihuana or tetrahydrocannabinols. The creation of a new drug code in the DEA regulations for marihuana extracts will allow for more appropriate accounting of such materials consistent with treaty provisions." *Id.* at 90,195. The notice indicates "[e]xtracts of marihuana will *continue* to be treated as Schedule I controlled substances." *Id.* at 90,194 (emphasis added).

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Prior to this final rule, marihuana extracts were Schedule I controlled substances under federal law. After enactment of this final rule, marihuana extracts continue to be Schedule I controlled substances under federal law. As a result, no "new" substance has been designated as a controlled substance under federal law. The board declines to take any action as a result of the enactment of 21 C.F.R. section 1308.11(d)(58) or in response to your Petition.

Sincerely,

Andrew Funk, Pharm.D.
Executive Director
Iowa Board of Pharmacy

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Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

June 7, 2017

Mr. Olsen,

In response to your open records request dated June 4, 2017, I have enclosed the documentation received by the Board regarding the assignment of a New Drug Code for Marihuana Extract by the DEA.

The letter you received was sent in my capacity as the Executive Director acting on behalf of the Board; it was not the result of a Board meeting or discussion among Board members. Therefore, there are no meeting minutes responsive to your request. Because your question involved a legal interpretation as opposed to a discretionary decision, my response was generated based on an analysis of the pertinent statutes and rules by the assistant attorney general assigned to represent the Board.

Sincerely,

Andrew Funk, Pharm.D.

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State of Iowa
Board of Pharmacy

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MINUTES

February 17, 2010

The Iowa Board of Pharmacy met on February 17, 2010, in the conference room at 400 SW Eighth Street, Des Moines, Iowa at 9:00 a.m. Chairperson Benjamin called the meeting to order at 9:02 a.m.

MEMBERS PRESENT
Vernon H. Benjamin, Chairperson
Susan M. Frey, Vice-Chair
Mark M. Anliker
Annabelle Diehl
Edward L. Maier
Peggy M. Whitworth

MEMBERS ABSENT
DeeAnn Wedemeyer Oleson

STAFF PRESENT
Lloyd Jessen, Executive Director
Scott Galenbeck, Esq., Assistant Attorney General
Therese Witkowski, Executive Officer
Debbie Jorgenson, Administrative Assistant
Becky Hall, Secretary

Compliance Officers Present:
Bernie Berntsen
Jim Wolfe

I. Medical Marijuana.

After the Board held four public meetings and reviewed a substantial amount of medical marijuana material, the Board met to deliberate the possible reclassification of marijuana from Schedule I of the Iowa Controlled Substances Act (Act) into Schedule II of the Act.

Motion (Maier/Anliker) the Iowa Board of Pharmacy recommends that the legislature reclassify marijuana from Schedule I of the Iowa Controlled Substance Act (Act) into Schedule II of the Act with the further recommendation that the legislature convene a task force or study committee comprised of various disciplines including but not limited to the following: a representative of a seriously ill patient; a representative of law enforcement; a representative of the Iowa Attorney General; a representative of an HIV organization or a physician caring for an AIDS patient; a

substance abuse treatment representative; a person living with a serious illness; a hospice or palliative care representative; a representative of the Iowa Board of Nursing; a representative of the Iowa Board of Medicine; and a representative of the Iowa Board of Pharmacy, for the purpose of making recommendations back to the legislature regarding the administration of a medical marijuana program. Roll call vote. Yes: Anliker, Benjamin, Diehl, Frey, Maier, Whitworth; No: None; Abstain: None; Absent: Oleson. Passed: 6-0-0-1.

Motion (Maier/Frey) to adjourn the meeting. Passed: 6-0-0-1. Absent: Oleson. Meeting adjourned at 12:47 p.m. on February 17, 2010.

Becky Hall

Becky Hall
Recording Secretary

Lloyd K. Jessen
Executive Director

Vernon H. Benjamin
Board Chair

APPROVED THIS 9th DAY OF March, 2010.

IDPH News Release

FOR IMMEDIATE RELEASE
2/17/10

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Iowa Board of Pharmacy Issues Recommendation

Board endorses marijuana as Schedule II drug for medical uses

The Iowa Board of Pharmacy today issued a recommendation that the Iowa Legislature reclassify marijuana from Schedule I of the Iowa Controlled Substances Act into Schedule II of the Act. A Schedule II drug includes narcotic drugs with a high potential for abuse but with currently accepted medical use in treatment.

In addition, the Board of Pharmacy is recommending the Legislature convene a task force or study committee for the purpose of making recommendations back to the Legislature regarding the administration of a medical marijuana program. The Board recommends the task force or committee be comprised of various disciplines including but not limited to the following: a representative of a seriously ill patient; a representative of law enforcement; a representative of the Iowa Attorney General; a representative of an HIV organization or a physician caring for an AIDS patient; a substance abuse treatment representative; a person living with a serious illness; a hospice or palliative care representative; a representative of the Iowa Board of Nursing; a representative of the Iowa Board of Medicine; and a representative of the Iowa Board of Pharmacy.

Rescheduling of marijuana is the first step of a process that could ultimately result in legalization for medical purposes. The Board of Pharmacy's recommendation to the Iowa Legislature does not impact current Iowa law.

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SENATE/HOUSE FILE _____
BY (PROPOSED DEPARTMENT OF PUBLIC HEALTH/BOARD OF PHARMACY BILL)

A BILL FOR

An Act revising the controlled substances schedules, and providing penalties.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

S.F. _____ H.F. _____

Section 1. Section 124.204, subsection 4, paragraph m, Code 2011, is amended by striking the paragraph.

Sec. 2. Section 124.204, subsection 4, paragraph u, unnumbered paragraph 1, Code 2011, is amended to read as follows:

Tetrahydrocannabinols, ~~except as otherwise provided by rules of the board for medicinal purposes,~~ meaning tetrahydrocannabinols naturally contained in a plant of the genus Cannabis (Cannabis plant) as well as synthetic equivalents of the substances contained in the Cannabis plant, or in the resinous extractives of such plant, and synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, such as the following:

Sec. 3. Section 124.204, subsection 4, Code 2011, is amended by adding the following new paragraph:

NEW PARAGRAPH. *ai.* 5-methoxy-N,N-dimethyltryptamine. Some trade or other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole;5-MeO-DMT.

Sec. 4. Section 124.204, subsection 7, Code 2011, is amended by striking the subsection.

Sec. 5. Section 124.204, subsection 9, Code 2011, is amended to read as follows:

9. *Other materials.* Any material, compound, mixture, or preparation which contains any quantity of the following substances:

~~*a.* N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers.~~

~~*b.* N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers.~~

a. 5-(1,1-Dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol. Other names: CP-47,497.

b. 5-(1,1-Dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-

phenol. Other names: cannabicyclohexanol and CP-47,497 C8 homologue.

c. 1-Butyl-3-(1-naphthoyl)indole. Other names: JWH-073.

d. 1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthoyl)indole. Other names: JWH-200.

e. 1-Pentyl-3-(1-naphthoyl)indole. Other names: JWH-018 and AM678.

Sec. 6. Section 124.206, subsection 6, Code 2011, is amended by adding the following new paragraph:

NEW PARAGRAPH. *c.* Immediate precursor to fentanyl: 4-anilino-N-phenethyl-4-piperidine (ANPP).

Sec. 7. Section 124.206, subsection 7, paragraph a, Code 2011, is amended to read as follows:

a. Marijuana ~~when used for medicinal purposes pursuant to rules of the board~~.

Sec. 8. Section 124.208, subsection 6, Code 2011, is amended by adding the following new paragraphs:

NEW PARAGRAPH. *bh.* Boldione (androsta-1,4-diene-3,17-dione).

NEW PARAGRAPH. *bi.* Desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst-2-en-17[beta]-ol); also known as madol.

NEW PARAGRAPH. *bj.* 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione).

EXPLANATION

This bill revises the lists of drugs on the controlled substances schedules, and provides penalties.

The bill removes marijuana from schedule I and reclassifies it as a schedule II controlled substance. The bill also strikes references to the authority of the board of pharmacy to adopt rules for the use of marijuana or tetrahydrocannabinols for medicinal purposes. A schedule I controlled substance is a highly addictive substance that has no accepted medical use in the United States and a scheduled II controlled substance is a highly addictive substance that has an accepted medical use in

the United States.

The reclassification of marijuana from a schedule I controlled substance to a schedule II controlled substance permits a physician to issue a prescription for marijuana.

The bill also revises the lists of drugs in the controlled substance schedules to conform with action undertaken by the federal drug enforcement administration. The bill classifies five synthetic cannabinoids, more commonly known as "K2", as schedule I controlled substances. The bill adds a drug commonly referred to as 5-MeO-DMT to the list of schedule I controlled substances as well. The bill also removes benzylfentanyl and thenylfentanyl from the schedule I classification. The bill classifies the substance ANPP, a precursor substance to the controlled substance fentanyl, as a schedule II controlled substance. The bill classifies three anabolic steroids as schedule III controlled substances. A controlled substance classified as a schedule III substance is a substance that has potential for abuse which is less than schedule I and II substances but has an accepted medical use in the United States.

It is a class "C" felony pursuant to Code section 124.401, subsection 1, paragraph "c", subparagraph (8), for any unauthorized person to violate a provision of Code section 124.401 involving a classified substance placed on schedule I, II, or III pursuant to the bill. The penalties remain unchanged for marijuana under the bill. The penalties under Code section 124.401 range from a class "B" felony punishable by up to 50 years of confinement to a serious misdemeanor punishable by up to six months of confinement depending on the amount of marijuana involved in the offense.