BEFORE THE IOWA MEDICAL CANNABIDIOL BOARD

Update by Carl Olsen
Federal Exemption

Carl Olsen
130 NE Aurora Ave
Des Moines, IA 50313-3654
515-343-9933
carl@carl-olsen.com

Implementation of HF 2589, Sec. 31 (2020):

On May 21, 2021, Mr. Olsen submitted four letters to the Medical Cannabidiol Board sent by the Iowa Department of Public Health pursuant to 2020 Iowa Acts Chapter 1116, Section 31 (HF 2589), requesting federal funding guarantees for state authorized activities.

A. Medicare and Medicaid
B. Food and Drug Administration
C. Department of Education
D. Drug Enforcement Administration ("DEA" hereafter)

Federal Exemption:

Federal exemption would guarantee federal protection of state authorized use of cannabis. Federal exemption, like the exemption that currently exists for peyote, 21 C.F.R. § 1307.31, would reconcile state and federal drug law where the state and federal drug laws create a positive conflict between state and federal drug laws.

Mr. Olsen has maintained that if a federal remedy exists, the state is morally and ethically bound to pursue it. If the DEA denies such a request, then the DEA is responsible for maintaining the conflict and the state is no longer abandoning the patients this law, Iowa Code Chapter 124E, was intended to protect.

Federal Funding:

In 2020, Mr. Olsen presented the Medical Cannabidiol Board with an article from the Sun Journal, *Federal mental health grants canceled because Maine has legal marijuana*, by Steven Colins, May 15, 2020. A copy of that article is attached to this Update. The article reported that SAMHSA (U.S. Substance Abuse and Medical Health Services Administration) denied $3.3 million in already approved funding to support mental health programs for youngsters in Maine.

Within the last couple of weeks, effective August 1, 2021, SAMHSA has clarified that policy and will no longer deny funding as long as the funding isn't being used to purchase, prescribe, or provide marijuana or treatment using marijuana. See attached letters from Pennsylvania Department of Drugs and Alcohol Programs, dated June 1, 2021, and August 2, 2021, respectively.

Mr. Olsen now speculates that the Iowa Department of Public Health may receive similar responses to the four letters it sent, essentially resolving those issues as a simple previous misunderstanding of federal requirements. Mr. Olsen can't be sure, but it appears that this issue is now moot.

Remaining Issues:

On June 28, 2021, U.S. Supreme Court Justice Clarence Thomas described the inconsistencies between state and federal drug law which he finds to be of most significance (he does not mention federal funding for grant recipients).

https://www.supremecourt.gov/opinions/20pdf/20-645_9p6b.pdf

Justice Thomas was responding to the particularly egregious federal tax penalty for unlawful income from drug trafficking. Justice Thomas does not even mention federal funding for state recipients of federal grants, because it has never been the bulk of this state and federal inconsistency.

Federal Legislation:

The federal legislature is considering various solutions. The most recent of those is the Cannabis Administration and Opportunities Act. Senate Democrats are asking for input before September 1, 2021, and the Medical Cannabidiol Board may be interested in providing input.

https://www.democrats.senate.gov/imo/media/doc/CAOA%20Detailed%20Summary%20-.pdf

Unlike a federal exemption, which would remove the federal tax penalty, the Senate Democrats would like to replace it with a 25% federal excise tax. Obviously, this one size fits all approach is targeted at so-called "recreational" use of cannabis. But Iowa does not have so-called "recreational" use of cannabis. The Cannabis Administration and Opportunities Act would erase the line between so-called "medical" use and so-called "recreational" use and tax both of them at the same 25% tax rate, which is clearly not what our legislature intended.

Congress has extended protection for state "medical" cannabis programs since 2015 in the annual federal budget and has refused to extend that same protection for "recreation" cannabis programs.

Consolidated and Further Continuing Appropriations Act, 2015 (H.R. 83), Public Law 113-235, § 538, 128 Stat. 2129, 2217 (Dec. 16, 2014); Consolidated Appropriations Act, 2016 (H.R. 2029), Public Law 114-113, § 542, 129 Stat. 2241, 2332 (Dec. 18, 2015); Consolidated Appropriations Act, 2017 (H.R. 244), Public Law 115-31, § 537, 131 Stat. 135, 228 (May 5, 2017); Consolidated Appropriations Act, 2018 (H.R. 1625), Public Law 115-141, § 538, 132 Stat. 347, 444 (Mar. 23, 2018); Consolidated Appropriations Act, 2019 (H.J. Res. 31), Public Law 116-6, § 537, 133 Stat. 13, 138 (Feb. 15, 2019); Consolidated Appropriations Act, 2020 (H.R. 1158), Public Law 116-93, § 531, 133 Stat. 2317, 2431 (Dec. 20, 2019); Consolidated Appropriations Act, 2021 (H.R. 133), Public Law 116-260, § 531, H.R. 133 (Dec. 27, 2020); Commerce, Justice, Science, and Related Agencies Appropriations Act, 2022 (H.R. 4505), § 531.

Mr. Olsen would like the Medical Cannabidiol Board to request that the Iowa Medical Cannabidiol Program be exempt from any proposed new federal excise tax.

Federal Regulation:

It is also worth noting that the Food and Drug Administration has just denied dietary supplement classification for Charlotte's Web. Charlotte's Web was the reason 2014 Iowa Acts Chapter 1125 was enacted. Marijuana extracts were to be obtained from an out-of-state source because Charlotte's Web was produced in Colorado. Iowa Code § 124D.6(1)(b) (2014). The FDA letter dated July 23, 2021, is attached here to.

Thank you!

Signed this 13th day of August, 2021.

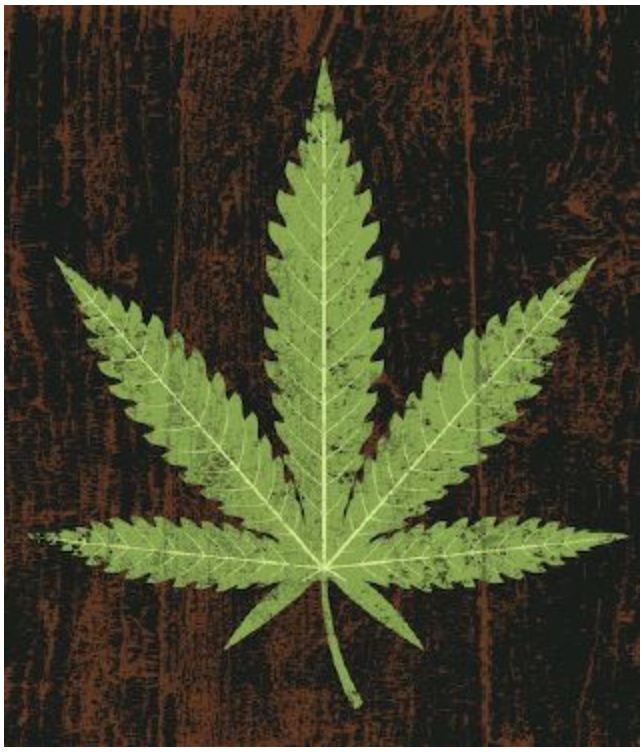
Carl Olsen
130 E Aurora Ave
Des Moines, IA 50313-3654
515-343-9933
carl@carl-olsen.com

cc: Governor Kim Reynolds
State Senator Jack Whitver
State Senator Brad Zaun
State Representative Pat Grassley
State Representative Jarad Klein

Federal mental health grants canceled because Maine has legal marijuana

SJ sunjournal.com/2020/05/15/federal-mental-health-grants-canceled-because-maine-has-legal-marijuana/

By Steve Collins May 15, 2020



Because Maine allows the medical use of marijuana by students, the federal government is cutting off $3.3 million in already approved funding to support mental health programs for youngsters.

It isn't clear whether the new federal policy may impact other grants received by the state.

The state won a five-year federal grant in 2018 that provided $1.1 million annually for a program called Maine-AWARE to assist in bolstering the social service infrastructure to support student mental health in three districts across the state.

Maine received the money for the first two years, but recently learned it won't get any more due to a policy change in Washington that cuts off states that allow students access to medical marijuana.

Pender Makin, the state commissioner of education, said in a May 6 email to a local superintendent that "a new requirement" on the federal level cut off the funding in its third year "because of our state's medical marijuana law, which requires schools to allow students who have written certification from their medical provider indicating their need for medical marijuana to receive such treatment while at school."

Makin said Maine has a statutory obligation to permit students to use medical marijuana if they possess the necessary prescription for it.

The federal Department of Health and Human Services, which handles the Advancing Wellness and Resiliency in Education grant, also known as AWARE, did not respond to requests for comment Thursday or Friday.

Kelli Deveaux, director of communications for the state Department of Education, said Friday that officials don't know yet if other grants may be impacted "by this new and arbitrary requirement."

The loss of federal aid is a setback for a state that is trying to cope with an alarming amount of mental health issues among students.

A research letter published a year ago in JAMA Pediatrics found that Maine had the highest rate in the country of children diagnosed with depression, anxiety or attention deficit disorder.

More than one in four Maine children ages 6 to 17 had at least one of the disorders, the study found. About half of them did not receive needed treatment or counseling from a mental health professional, the researchers found.

The federal Health and Human Services division that canceled the grant, the Substance Abuse and Mental Health Services Administration, said the program it had funded focuses on "partnerships and collaboration between state and local systems to promote the healthy development of school-aged youth and prevent youth violence."

RSU 10 Superintendent Deb Alden in Rumford, whose district got $200,000 in each of the past two years through the grant, called the abrupt end to the program "just really disheartening."

The decision to clamp down on states that allow the use of marijuana appears to be part of a larger effort by President Donald Trump's administration to punish states that haven't toed the line on the federal government's long-standing policy of treating marijuana as an illegal drug. It may impact grants related to the opioid crisis as well.

The substance agency, in many presentations, has made clear that it considers marijuana a dangerous drug that can lead to poor school performance, increased risk of motor vehicle accidents, cognitive impairment and other problems.

There are at least 33 states that allow medical marijuana. Following a 2016 state referendum where voters chose to legalize the drug, Maine is one of about a dozen that allow recreational use of marijuana as well, though not by minors.

Makin said in her email to Alden that Maine's medical marijuana law allows people to receive a medical certification for any diagnosis if a medical provider says it is "likely to have a therapeutic or palliative benefit."

Another state law provides that students who have a medical marijuana card cannot be denied the right to attend school solely because they need medical marijuana, in a nonsmokable form, while they're at school.

"Because of these provisions in Maine law, we are ineligible for participation in the AWARE grant program" after Sept. 30, she wrote, when the new federal fiscal year begins.

The move means that three districts who received funding through the project – RSU 10 in Rumford, RSU 20 in Searsport, and the Calais School Department – won't receive any more of the federal cash for the third, fourth and fifth years of their pilot programs.

According to the state, the primary goals of the Maine-AWARE initiative are to ensure all students have access to evidence-based social emotional learning strategies, positive behavioral interventions and screenings.

It also aims to identify students and families with increased risk of "negative academic and behavioral outcomes" with targeted interventions, team-based school and community supports and mental health screening.

Clinical interventions for some young people and their families who are "experiencing serious mental or behavioral disorders" is also part of the effort.

Whether the programs in the three districts can survive without federal funds is uncertain.

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DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

Information Bulletin **01-21**

Ellen DiDomenico
Deputy Secretary
Department of Drug and Alcohol Programs

June 2, 2021

Effective Date: Immediately
Subject: Clarification on special conditions for federal funding related to medical marijuana

Beginning in September 2019, the Substance Abuse and Mental Health Services Administration (SAMHSA) has been including the following special conditions in federal funding awards:

> *Grant funds may not be used, directly or indirectly, to purchase, prescribe, or provide marijuana or treatment using marijuana. Treatment in this context includes the treatment of opioid use disorder. Grant funds also cannot be provided to any individual who or organization that provides or permits marijuana use for the purposes of treating substance use or mental disorders. See, e.g., 45 C.F.R. § 75.300(a) (requiring HHS to "ensure that Federal funding is expended . . . in full accordance with U.S. statutory . . . requirements."); 21 U.S.C. §§812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana). This prohibition does not apply to those providing such treatment in the context of clinical research permitted by the DEA and under an FDA-approved investigational new drug application where the article being evaluated is marijuana or a constituent thereof that is otherwise a banned controlled substance under federal law.*

These special conditions apply to subrecipients of these funds and are included in contracts with Single County Authorities and providers.

Recently, SAMHSA provided the attached document with further clarification to the Department. SAMHSA has clarified that the grant condition does not apply to all use of medical marijuana, but only to medical marijuana used for treatment of a mental or substance use disorder. In addition, if a large system (e.g. a hospital) receives SAMHSA funds, the prohibition applies only to the department that receives the funds. Recipients of SAMHSA funds may continue to serve clients who use medical marijuana for a mental or substance use disorder as long as they document the client's understanding of the risks of marijuana use and willingness to work toward other, evidence-based alternatives to treat their mental or substance use disorder.

Questions regarding this Information Bulletin can be sent to RA-DAGRANTSMGMT@pa.gov.

SAMHSA
Substance Abuse and Mental Health Services Administration
5600 Fishers Lane • Rockville, MD 20857
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

January 1, 2020

Follow-Up on Notice of Award Term

1. Does the new condition on my Notice of Award (NoA) regarding marijuana use relate to all medical marijuana use?

Response: No. The condition relates specifically to the use of marijuana for the treatment of mental or substance use disorders.

2. If a person tests positive for marijuana use, do I need to dismiss them from my program in order to continue to receive SOR dollars?

Response: No. SAMHSA understands that polysubstance use is the rule and not the exception for most patients. The person can remain in treatment and the provider must work with the individual to understand the risks of marijuana use and address the patient's use in the treatment plan.

3. Can a patient receive medical marijuana for a mental or substance use disorder from my SAMHSA-grant funded facility?

Response: No. In the case of a large system, the rule applies to the department in the system receiving SAMHSA funds (an ED in a hospital for example).

4. Can a patient receive medical marijuana for mental or substance use disorders elsewhere and still be a patient in my SAMHSA-grant funded facility?

Response: Yes, but the clinician must document that the patient is willing to work with the practitioner to understand the risks of the marijuana use and be willing to work toward using evidence-based alternatives to treat their mental/substance use disorder. SAMHSA understands that abstaining from the use of marijuana for mental or substance use disorders may take time; the organization simply has to document it work with the patient in this regard.

5. What if the patient is very clear about their wish to remain on their medical marijuana for their mental or substance use disorder—in this instance can the organization serve them?

Response: No. The organization cannot serve a patient who is on medical marijuana for a mental or substance use disorder and wishes to remain on such treatment. SAMHSA promotes the use of evidence-based practices and there is no evidence for such a treatment; in fact, there is increasing evidence that marijuana can further exacerbate mental health symptoms. Further, SAMHSA believes the use of marijuana for these conditions in a treatment program designed to treat these conditions can compromise the therapeutic environment for those patients receiving services who wish to remain

abstinent, use evidence-based treatment approaches and achieve recovery. The practitioner should be very clear with the patient regarding the risk of being dismissed from the program if the patient chooses to remain on medical marijuana for mental/substance use disorder. If a patient is adamant about their desire to remain on medical marijuana for mental or SUDs despite the clinician's efforts, the program should work with the patient to find an alternative non-SAMHSA funded program.

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DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

Information Bulletin **02-21**

Ellen DiDomenico
Deputy Secretary
Department of Drug and Alcohol Programs

August 2, 2021

Effective Date: Immediately

Subject: Updated SAMHSA term and condition for marijuana

Effective August 1, 2021, the Substance Abuse and Mental Health Services Administration's (SAMHSA) term and condition for marijuana has been updated. The updated term is as follows:

> *SAMHSA grant funds may not be used to purchase, prescribe, or provide marijuana or treatment using marijuana. See, e.g., 45 C.F.R. 75.300(a) (requiring HHS to ensure that Federal funding is expended in full accordance with U.S. statutory and public policy requirements); 21 U.S.C. 812(c)(10) and 841 (prohibiting the possession, manufacture, sale, purchase or distribution of marijuana).*

The updated term **no longer** includes the second piece of prohibition: "Grant funds also cannot be provided to any individual who or organization that provides or permits marijuana use for the purposes of treating substance use or mental disorders."

These special conditions apply to subrecipients of these funds and are included in contracts with Single County Authorities and providers.

Questions regarding this Information Bulletin can be sent to RA-DAGRANTSMGMT@pa.gov.

July 23, 2021

Mr. Tim Orr
Charlotte's Web, Inc.
1600 Pearl Street
Boulder, Colorado 80302

Dear Mr. Orr:

This letter is to inform you that the notification that you submitted pursuant to 21 United States Code (U.S.C.) § 350b(a)(2) (section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)), was received and filed by the Food and Drug Administration (FDA or we) on March 31, 2021. Additional information was received on May 7, May 12, and June 21, 2021. The amendment received on May 12, 2021, was deemed a substantive amendment, which reset the filing date to May 12, 2021, as per 21 CFR 190.6(d). Your notification concerns the new dietary ingredient (NDI) "Charlotte's Web Full Spectrum Hemp Extract" (CW FSHE) (hereinafter "NDI 1202") that you intend to market in a dietary supplement tincture.

According to your notification, the conditions of use are: "The proposed maximum daily intake of dietary supplement tincture is two (2) servings per day. Each 0.15 mL serving of the tincture provides 12.9 mg of the CW FSHE extract (9.75 mg CBD). Suggested daily intake is 0.30 mL of the tincture providing 25.8 [mg of the] CW FSHE [extract] (19.5 mg CBD). Duration of use is intermittent. Target population is adults (18+ years) with instructions to consult your physician before use if you are pregnant, nursing, have or suspect a medical condition or are taking any medications. Also includes instructions to keep out of the reach of children."

Under 21 U.S.C. § 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. § 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the condition recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. § 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your notification and other available information and determined that your NDI 1202 cannot be used in dietary supplements pursuant to the dietary supplement exclusion provision in 21 U.S.C. § 321(ff)(3)(B) (section 201(ff)(3)(B) of the Act). The definition of a dietary supplement is set forth in 21 U.S.C. § 321(ff) (section 201(ff) of the Act), which states in relevant part:

> (ff) The term 'dietary supplement' . . . (3) does . . . (B) not include – (i) an article that is approved as a new drug under section 355 of this title . . . or (ii) an article authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,
>
> which was not before such approval . . . or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

FDA has concluded that CBD products are excluded from the dietary supplement definition under 21 U.S.C. § 321(ff)(3)(B) (section 201(ff)(3)(B) of the Act). CBD is the active ingredient in the approved drug product, Epidiolex. Furthermore, the existence of substantial clinical investigations involving CBD has been made public. FDA has also determined that CBD was not marketed as a dietary supplement or conventional food before it was authorized for investigation as a new drug.[1] FDA has concluded based on the record that your NDI 1202 is carefully designed to ensure consistent levels of CBD, and that it is produced from your proprietary (b) (4) that provide robust levels of CBD. In addition, your NDI 1202 contains a significant amount of CBD per mL and you also appear to market "full-spectrum hemp extract"-containing products as CBD products. Looking at the totality of the record, FDA has concluded that your NDI 1202 is a CBD product and thus is subject to the exclusion from the definition of dietary supplement under 21 U.S.C. § 321(ff)(3)(B). Accordingly, your product may not be marketed as or in a dietary supplement.

We also conclude that, even if your NDI 1202 was not excluded from the definition of dietary supplement, the agency has concerns about the adequacy of safety evidence included in your submission as a basis for concluding that a dietary supplement containing NDI 1202 will reasonably be expected to be safe under the conditions of use described in your notification. The notification included some evidence intended to show adequate history of safe use and also included reports of safety studies. These categories of evidence had deficiencies on their own and, even when all of the evidence was considered as a whole, the notification failed to show that the NDI will reasonably be expected to be safe. For example, your submission provided two years of marketing for NDI 1202 as evidence of history of use, which is insufficient to establish the safety of your ingredient when used under the proposed conditions of use. Furthermore, FDA was unable to accept your proposed no-observed adverse effect level (NOAEL), which was based on the publication by Dziwenka et al., 2020, because the publication included inadequate information for the purposes of assessing the reliability of the conclusions in the publication.

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[1] *See* "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)," available at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#dietarysupplements

FDA requested that you provide the agency with the supporting or underlying data that formed the basis for the Dziwenka et al. 2020 study, but you did not provide FDA with this data. In addition, none of the clinical and pre-clinical studies that you provided adequately address certain reported toxicity endpoints of CBD such as hepatotoxicity and reproductive toxicity. For these reasons, the information in your submission indicates that, even if your NDI 1202 were not excluded from the definition of a dietary supplement, your notification does not provide an adequate basis to conclude that a dietary supplement containing the ingredient, when used under the proposed conditions of use, would reasonably be expected to be safe. Therefore, if it were a dietary supplement, a product containing your NDI 1202 may be adulterated under 21 U.S.C. § 342(f)(1)(B) (section 402(f)(1)(B) of the Act).

If you have additional or new information that has a bearing on the issues discussed in this letter, you may present it to FDA for our consideration.

Your notification will be kept confidential for 90 days after the filing date of May 12, 2021. After the 90-day date, the notification will be placed on public display at www.regulations.gov as new dietary ingredient notification report number 1202. Prior to that date, you may wish to identify in writing specifically what information you believe is trade secret or confidential commercial information and include an explanation of the basis for this belief.

If you have any questions concerning this matter please contact Jeanne Skanchy, R.Ph, by email at NDITEAM@fda.hhs.gov.

Sincerely,

Cara Welch -S Digitally signed by Cara Welch -S
Date: 2021.07.23 16:21:11 -04'00'

Cara Welch, Ph.D.
Acting Director
Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition