

Drug Enforcement Administration

PETITION FOR EXEMPTION

August 27, 2020

**Exhibit #4**



**Iowa Department of Public Health**  
**Protecting and Improving the Health of Iowans**

Gerd W. Clabaugh, MPA  
 Director

Kim Reynolds  
 Governor

Adam Gregg  
 Lt. Governor

**DRAFT Notes**  
**Iowa Medical Cannabidiol**  
**Board August 2, 2019**  
**10:00 a.m.**  
**Iowa Laboratory Facility – DMACC**  
**Campus 2240 DMACC Blvd.**  
**Ankeny, IA**

1. **Call to Order** **Mike McKelvey, Chair**  
 The August 2, 2019, Iowa Medical Cannabidiol Board meeting was officially called to order at 10:00 a.m.
2. **Roll Call** **Mike McKelvey, Chair**

Members Present	Members Absent
Dr. Ken Cheyne – Pediatrician	Vacant – Gastroenterologist
Dr. Jill Liesveld – Psychiatrist	Vacant - Neurologist
Capt. Mike McKelvey – Law Enforcement	
Dr. Lonny Miller – Family Medicine – <i>via conference call</i>	
Dr. Stephen Richards – Pharmacist	
Dr. Bob Shreck – Oncology	
Dr. Jacqueline Stoken – Pain Management	
Staff	
Sarah Reisetter – Deputy Director, IDPH	
Randy Mayer - Director	
Owen Parker – Program Manager	
Jennifer Caskey – Recording Officer	

3. **Approval of Minutes** **Mike McKelvey, Chair**
  - a. **April 16, 2019, Medical Cannabidiol Board Meeting**  
 Dr. Stoken motioned to approve the April 16, 2019 meeting minutes, with a second by Dr. Shreck.  
  
 A verbal vote was taken. Motion carried unanimously.

4. **Public Comment Period** **Mike McKelvey, Chair**
  - **Casey Ficek, Iowa Pharmacy Association** – Addressed the Board and requested that, as they consider 2019 and are looking to 2020, to recommend supporting pharmacists and pharmacy techs in our licensed dispensaries.
  - **Rebecca Lucas, MedPharm Iowa** – Addressed the Board and expressed that MedPharm has patients

ranging in age from 2 to 102. They have pediatric patients who experience benefit from THC-containing products, and oppose the recommended pediatric restrictions on THC. She spoke to the differences between ages and conditions in pediatric patients. She provided feedback on variable responses of patients to medical cannabidiol, and expressed that some do report psychoactive effects. She invited the Board to visit their dispensaries to develop an understanding of their processes, as well as invited them for another tour of their manufacturing facility.

- **Lucas Nelson, MedPharm Iowa** – Expressed that the program is at a critical inflection point, and mentioned Illinois passing adult use and Gov. Reynolds’ veto of HF732. He expressed the need to give suffering patients relief. He noted that Iowa is a medical cannabis program, and expressed that the legislative intent was not to have only a CBD program. He recommended setting up a bipartisan committee to review expansion of the program, using science and best practices from other states, and to also include patients. He recommended expansion of access to THC for Iowa, and that it should be determined by the needs of the patients and their conditions. He expressed that 25 grams should be allowed. He expressed for there to be a thorough look at laboratory testing and procedures.
- **Arin Bollman, Caregiver of Patient** – Expressed concern with the recommendation to limit the dose of THC for pediatric patients. She expressed that the current dosage she is using for her child is working, but implementing a THC restriction for pediatric patients would force them not only to lower his dose, but will cost them significantly more money each month. She expressed that the patient has issues with aggression, and shared that she must currently visit her son at school and take him off facility grounds to administer his medication.
- **David Barnett, Program Patient** – Mr. Barnett is a patient and works with Balanced Veterans, a non-profit who works to educate veterans on medical cannabis. He spoke to the group regarding the psychoactive effects of THC, but also noted that the medications that are currently prescribed for PTSD can have similar or worse effects, yet are legal. He shared information on other psychiatric medications, and shared his opinion that cannabis has a much better safety profile.
- **Sen. Joe Bolkcom, Iowa Senate (43<sup>rd</sup> District)** – Sen. Bolkcom shared his opinion that the Board and the Governor’s office have created the worst medical cannabis program in the US. He shared statistics and stated patients want greater choice, and expressed that there must be better access for rural Iowans. He shared the number of narcotic prescriptions dispensed in Iowa versus the number CBD patients and total purchases. He spoke to Illinois starting an adult use market, and stated that it was good news for Iowans who want to travel to Illinois instead of Colorado, but that it will ruin Iowa’s program and put patients in legal jeopardy.
- **Tyler Rice, Private Citizen** – Shared personal story of work history as a police officer, as well as history with mental health. He shared the side effects of prescription medications that were severe enough to make him stop using the medication. He shared personal use of CBD and how it has benefited his PTSD.
- **Christina Savage-Doolittle, Program Patient** – Shared her personal stories of suffering from PTSD. She noted a history of various forms of abuse and trauma, leading to pharmaceutical medications. She expressed the need to allow PTSD and opioid dependent Iowans access to CBD.
- **Ray Lakens, Private Citizen** – He expressed in 2009 there were four public hearings on medical cannabis that included patients. During the Culver administration, he noted he was asked to be on a patient advisory board. He expressed that he does not like to take prescribed MS medications because of their side effects. Noted that there are 3000 patients in the program, but the road blocks being created will force patients to purchase products in Illinois.

- **Rep. John Forbes, Iowa House of Representatives (40<sup>th</sup> District)** – Rep. Forbes expressed deep regret for the Board’s recommendation to the Governor to veto HF732. He spoke to the bipartisan work to get the bill written and passed. He shared the vote totals, and stated his hypothesis that opposition was due to expanding the THC limit. He expressed that Iowa does not currently have a THC limit, and noted that the bill would have instituted this purchase limit. He noted that some patients need 50 – 150 mg of THC/day for their pain management. He shared a story of patient using Oxycodone and Oxycontin, and that he spoke with her about enrolling in the medical cannabidiol program after he saw she was having issues and a decline in her quality of life. He expressed that she is enrolled in the program and is now off narcotics.
- **Wendy Borchardt, Program Patient** – Shared her personal history of abuse and substance abuse throughout childhood, adolescence, adulthood. She expressed that THC and CBD help relieve her symptoms. Expressed that prices are high and difficult for patients to afford.
- **Jennifer Husman, Private Citizen** – A prevention specialist, who thanked the board for being careful regarding THC. Expressed the benefit of Dr. Golgek’s presentation at the February 1, 2019 meeting. She shared the story of veteran who committed suicide and blamed marijuana. She shared THC levels from other states and talked about how THC has increased over the years.
- **Maggie Ballard, Private Citizen** – Expressed that she had spoken to the board in the past, and raised concerns with increasing the THC limit. She noted that it’s not the Board’s charge to save the licensed cannabis businesses.
- **Sen. Claire Celsi – Iowa Senate (21<sup>st</sup> District)** – Sen. Celsi expressed that many constituents have contacted her about this issue. She expressed that we are putting patients in a situation to self-medicate or break the law. She expressed that the Board should let the legislature take the heat of these decisions, and to not go down a path that is counter to most other states.
- **Peter Komendowski, Partnership for a Healthy Iowa** – He expressed that Iowa is a CBD program, not a medical marijuana program. He noted that Iowa does not need to follow what other states are doing. He expressed that Governor Reynolds’ veto was buyer’s remorse. He noted he had spoken with hundreds of Iowans who are happy that the board recommended to veto HF732.
- **Shelley Servadio, Private Citizen** – A registered nurse, cannabis nurse, and veteran. She shared a publication that contains research and articles from all over the world about PTSD and medical cannabis use, including research and dosing for PTSD from Israel. She noted having received treatment through the VA, and shared that other medications have not worked. She expressed that veterans would benefit from the use of CBD and THC, and that the Board needs to keep pace with what other states are doing and what the patients of Iowa are asking for.
- **Lindsay Gaunt, Caregiver of Patient** – The mother of an autistic program patient, whose child started on CBD in May at the highest dosages of CBD. She expressed that the high CBD helped with focus, but not aggression. She expressed that switching to high THC but has helped with both aggression and sleeping. She has found that balanced THC to CBD, or high THC, have been the most effective for her child.
- **Richard Mills, Program Patient** – A Parkinson’s patient and one of the first patients in Iowa. He expressed he has spoken across the nation regarding use of CBD for Parkinson’s disease. He expressed that patients will be forced to break the law in Illinois to get relief, and that Iowa should remove some of the many hurdles to become a patient.

Sarah Reisetter, Deputy Director at the Iowa Dept. of Public Health led the discussion regarding the five petitions received for the Board's consideration to add as approved conditions for the Iowa Medical Cannabidiol Program.

**a. Generalized Anxiety Disorder**

The petitioner was not present to address the Board. Dr. Liesveld, a psychiatrist, expressed that the literature in regards to medical cannabidiol's efficacy for the treatment of Generalized Anxiety Disorder is conflicting. She expressed that some patients report it helping, while other report that it worsened their condition. Medical literature supporting the use of medical cannabidiol for treatment Generalized Anxiety Disorder is not available.

A motion was made by Dr. Shreck, with a second by Dr. Liesveld to deny the addition of Generalized Anxiety Disorder as an approved debilitating condition. A verbal vote was taken:

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
McKelvey – aye  
Stoken - aye

Motion carried unanimously.

**b. PTSD**

The petitioner, Rebecca Lucas of MedPharm Iowa, reminded the board that they have been petitioned in the past to consider PTSD. She shared literature and expressed that some science shows the efficacy of medical cannabidiol for the treatment of Post-Traumatic Stress Disorder. The petitioner also expressed that Iowa is a compassionate use state, and that this is a compassion issue. Dr. Miller expressed that while scientific literature may be lacking, approving this condition could benefit some Iowans, and agreed with a stance of compassionate use. He expressed concerns about THC and paranoia, and that the Board could modify the petition to restrict it to patients who do not have a history of paranoia or psychosis. Dr. Shreck expressed appreciation to Dr. Miller for his approach and innovation. Dr. Shreck shared research from Canada and Minnesota which found little or no benefit of medical cannabidiol for the treatment of Post-Traumatic Stress Disorder, and also expressing that many patients have side effects and difficulties when reducing or stopping use. Dr. Shreck also cited an article from the Annals of Internal Medicine which showed that evidence for medical cannabidiol's benefit for the treatment of Post-Traumatic Stress Disorder is inconclusive, but is awaiting further reports from the trials. Dr. Shreck recommended waiting to make a decision on the petition until the Board could review the results from those trials.

A motion was made by Dr. Shreck, with a second by Dr. Stoken to defer the petition for the addition of PTSD as an approved debilitating condition to the November 1, 2019 meeting. A verbal vote was taken:

Cheyne – oppose  
Liesveld – oppose  
Miller – aye  
Richards – aye  
Shreck – aye

Stoken- aye  
McKelvey – aye

Petition will be placed on the agenda for the November 1, 2019 Board meeting.

**c. Schizophrenia, Borderline Personality Disorder, Rape Trauma, Social Phobia**

The petitioner was not present to address the Board. The Board expressed that Schizophrenia, Borderline Personality Disorder, Rape Trauma, Social Phobia is mixture of complex conditions, diagnoses, and treatment modalities. The medical literature to support the addition of Schizophrenia, Borderline Personality Disorder, Rape Trauma, Social Phobia is lacking.

A motion was made by Dr. Richards, with a second by Dr. Shreck to deny the addition of Schizophrenia, Borderline Personality Disorder, Rape Trauma, Social Phobia as an approved debilitating condition. A verbal vote was taken:

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried unanimously.

**d. Opioid Dependency, Tolerance, & Use Disorder**

The petitioner, Rebecca Lucas of MedPharm Iowa, expressed that they have numerous patients who are benefitting from medical cannabidiol as a treatment option for Opioid Dependency, Tolerance, & Use Disorder. She expressed this is done through reducing and tapering the frequency and dosage of opioids. Dr. Miller expressed that some of his own patients have been able to taper or reduce their dose of opioids with medical cannabidiol. Dr. Shreck expressed that in researching effective treatments for Opioid Dependency, Tolerance, & Use Disorder, the words THC or CBD do not appear and that there is no medical evidence supporting the use of medical cannabidiol for treatment of this disorder.

A motion was made by Dr. Liesveld, with a second by Dr. Stoken to deny the addition of Opioid Dependency, Tolerance, & Use Disorder as an approved debilitating condition. A verbal vote was taken:

Cheyne – oppose  
Liesveld – yes  
Miller – yes  
Richards – yes  
Shreck – yes  
Stoken – yes  
McKelvey – yes

Motion carried.

**e. Severe or chronic pain**

The petitioner, Rebecca Lucas of MedPharm Iowa, expressed that the condition as it reads is confusing for both patients and physicians. Dr. Miller suggested that the word “severe” should be removed and the board should consider the addition of “Chronic Pain” as a condition because CBD does not work for

treatment of acute pain. Board members expressed that some chronic pain patients may only exhibit moderate pain, but cannot take traditional NSAIDS like ibuprofen or acetaminophen. Additionally, the Board expressed that patients experiencing Severe Pain would be allowed to be certified under Chronic Pain.

A motion was made by Dr. Shreck, with a second by Dr. Liesveld to remove “Untreatable Pain” as an approved debilitating condition. A verbal vote was taken:

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried unanimously.

A motion was made by Dr. Cheyne, with a second by Dr. Shreck to MODIFY the petition and APPROVE the addition of Chronic Pain as an approved debilitating condition. A verbal vote was taken:

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried unanimously.

**6. Petition for Recommendation to the IDPH**

**Sarah Reisetter, Deputy Director**

The petitioner, Carl Olsen, had an opportunity to address the Board. The petitioner is asking the Board to recommend that the state board of health consider asking the DEA to recognize Iowa’s medical cannabis program as exempt from federal drug law in recognition of the state’s determination that marijuana does have a medical use by virtue of the adoption of Iowa Code chapter 124E. Board members asked the petitioner if he had discussed the matter with legislators. He shared that yes he had, and that an amendment passed in both subcommittee and full committee seeking to clarify that Iowa code chapter 124E does not conflict with any federal law.

A motion was made by Dr. Cheyne to forward the petition to the State Board of Health, with a recommendation for consideration; a second motion was made by Dr. Richards.

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried unanimously.

**7. Program Update & Review of State-by-State THC Limits**

**Owen Parker, Program Manager**

Mr. Parker gave an update to program data thus far. He provided a chart of application approvals by month, which is 350-450 per month. He reported on the conditions which Iowans are certified for, as well as that >70% of Iowans are certified for a pain-related condition. He reported that the average age of Iowa patients is >58 years, and that the gender breakdown is around 50% each for males and females. He showed that high THC products and balanced THC:CBD products are the most purchased products in the program thus far, and also provided state-by-state THC comparisons.

**8. Manufacturer & Dispensary Updates**

**a. Doug Bosswick & Sagar Patel, Iowa Relief**

Doug Bosswick, General Manager for Iowa Relief, gave an update on the staff that Iowa Relief has hired, as well as how they have completed their buildout and have formulated products. Iowa Relief is coming to market with a high CBD tincture, followed by a CBD and THC tincture late this fall.

**b. Shannon Cretsinger, Iowa Cannabis Co.**

Shannon thanked IDPH for the invitation to speak. Shannon expressed that they feel the THC levels need to be expanded to meet patient relief needs. Another improvement needed is to expand certifiers to include ARNPs and PAs, as well as the need to expand the list of debilitating conditions. She expressed that Iowa Cannabis Company is not seeing enough patients to make it a sustainable business.

**9. Iowa Podiatric Medical Society**

**Mike St. Clair, Lobbyist**

**a. Request for recommendation to add podiatrists as certifiers**

Mike St. Clair, lobbyist for the Iowa Podiatric Medical Society, introduced Dr. Mindy Dayton, a practicing podiatrist in Ankeny, IA. Dr. Dayton shared her background and experience as a Podiatrist, and expressed that much of the training and education is very similar to that of a DO or MD. She noted that podiatrists have much of the same prescribing authorization that physicians do. Dr. Miller asked if there are conditions other than pain that would qualify as a condition as seen by podiatric doctors, Dr. Dayton replied no, and said they are an integrated part of a healthcare team, and make referrals to appropriate physicians when necessary. Dr. Shreck noted that this topic was discussed at the April board meeting. Dr. Shreck said the Board should remove every obstacle they can, and that making patients going back to their primary care provider in these instances would be an obstacle.

Dr. Shreck made a motion to recommend that podiatrists be added to the definition of healthcare providers, with a second by Dr. Richards.

Cheyne – aye  
Liesveld – aye  
Miller – oppose  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried.

**10. Annual Report Recommendation Review**

**Board Members**

**a. Prior recommendations (2018 Annual Report)**



**1. Maintain THC cap of 3%**

Recommended to the legislature to maintain the 3% THC limit in 2017 and 2018.

Recommended removal of the 3% THC cap at the April, 2019 meeting. Board consensus is to recommend removal the 3% THC Cap.

**2. Removing felony disqualifiers for patients and caregivers**

The Board has made this recommendation for the past two years. Board consensus is to remove the felony disqualifier for patients and caregivers.

**3. Addition of PAs and ARNPs as certifiers**

Board consensus to add ARNPs and PAs to list of healthcare practitioners. This would now also include Podiatrists.

**4. Pharmacists and pharmacy techs in dispensaries**

There was Board consensus to move forward with a mandate for pharmacists and pharmacy techs to be in Iowa's dispensaries providing dosing recommendations. This was based on Minnesota having a similar model.

**5. Physician access to the patient registry**

There is Board consensus to allow physician access to the patient registry, similarly to a PMP.

**6. Use of medical cannabidiol products in long-term, acute care and school settings**

There was Board consensus to allow this and develop language to protect these facilities.

**7. Require (department) research**

Dr. Shreck recommended an observational study, with research on products being used by which patients for what conditions, as well as how the program is working for people.

**b. HF 732 proposed program changes, excluding prior recommendations**

**1. Remove "untreatable pain", replace with "severe and chronic pain"**

This was addressed during the petition for severe and chronic pain, with the motion to recommend removal of the Untreatable Pain condition as a qualifying debilitating medical condition.

**2. Restrict THC limit to 25g/90 days, with waiver provision for terminally ill**

Dr. Shreck expressed that the opinion of the Board is the still same as it was during the April, 2019 meeting, and to recommend – 4.5 grams of THC per 90 days. There was also Board consensus to include the waiver provision for the terminally ill.

Discussion regarding the 4.5 gram recommendation – It was posed to the Board that in the event policy makers want to go higher than the 4.5 g, are there other things related to patient safety that the Board would like the legislature to consider? Physician access to patient registry would be a safety issue that could be included. It was asked if the Department can track if patients are going to multiple dispensaries. IDPH system can currently do this, and could electronically stop sales in real-time to individual patients if necessary. The Board was asked to consider this between now and the next Board meeting, with the conversation expected to continue then.

**c. New 2019 Annual Report Recommendations**

**1. Restrictions on products sold to pediatric patients (from April, 2019 letter)**

Dr. Shreck expressed that Epidiolex, a pharmaceutical preparation of CBD, recommends twice

the dosage of CBD for pediatric patients that the Board did. Dr. Cheyne, a pediatrician, does not like this because some pediatric patients are adult-sized, and would define pediatrics up to age 21. There was Board consensus to remove this recommendation from the draft report, and will discuss it further at the November meeting.

## **2. THC purchase limit, including how to measure total THC**

The current statute definition of medical cannabidiol only addresses THC, and does not address THCa. When THCa is heated, it converts to THC. Other states have addressed this by measuring total THC, which will account for THCa when delivered in a combustible or vaporizable form. There was Board consensus that a recommendation to measure total THC concentration will be coupled with the gram recommendation limit discussed previously.

## **3. Requirement for DOT to issue registration card**

IDPH has received many messages from patients as to how this is a barrier to access. It was discussed how this requirement does not actually play a role in fraud prevention because of the other documentation that patients and caregivers must provide at the time of patient registry application. IDPH could step into the role of providing patient and caregiver registration cards, and eliminate the burden on ill patients to visit the DOT to get a registration card. There was Board consensus to recommend removing this requirement.

## **4. Limitation on the number of board meetings**

This topic was raised because of the Board needing to schedule an emergency meeting in April in order to discuss pending legislation. It was noted that the original number of meetings was to respect of the Board members' time. Dr. Cheyne recommended to allow for more meetings as needed, but keep it to four right now. There was Board consensus to keep meeting quarterly, but allow for more as necessary.

Cpt. McKelvey asked how much lead time the Board would like to be able to review the petitions properly, as well as if there was a limit to the number of times a condition can be proposed and considered in a year. The Board would like to have at least one month to review petitions. If petitions are submitted less than one month before a meeting, they would automatically be deferred to the next quarterly meeting.

## **5. Changing the name of the program to reflect a comprehensive program**

Dr. Miller expressed that the term Iowa Medical Cannabidiol Program was likely used to make program more palatable to some in the legislature. He made a recommendation to change the name of the program to something which accurately reflects that it is a comprehensive program that offers both THC and CBD products, such as The Office of Medical Cannabis. There was Board consensus to giving a name to the program that properly reflected the comprehensive nature of the program.

## **11. Appointment of a subcommittee of board members to explain the Board's recommendations to other key stakeholders**

Board meetings must be held in compliance with Iowa open meetings law. In the past, the number of members who could accept invitations to speak to various stakeholders has been restricted to avoid violations of the open meetings law. The appointment of a subcommittee that would be authorized to speak on behalf of the entire board limited to the board's formal recommendations was proposed. It was recommended that this subcommittee be appointed by Cpt. McKelvey as the need arises.

Dr. Richards made a motion to allow the Board chair to make subcommittee designations to speak on behalf of the board, with a second by Dr. Shreck.

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried unanimously.

**12. Appointment of a subcommittee to review petitions for new conditions**

It was discussed that Cpt. McKelvey could designate a subcommittees to review petitions and materials prior to a quarterly Board meeting, and the subcommittee could come to the full board with recommendations. The subcommittee assignments could rotate and might be open to the public in some manner.

Dr. Shreck made a motion to allow the Board chair to make subcommittee designations to review petitions for new conditions, with a second by Dr. Cheyne.

Cheyne – aye  
Liesveld – aye  
Miller – aye  
Richards – aye  
Shreck – aye  
Stoken – aye  
McKelvey – aye

Motion carried unanimously.

**13. Future Meetings**

**a. Friday, November 1, 2019**

**14. Adjourn**

**Mike McKelvey, Chair**