



April 16, 2019

RE: Comments on pending legislation

Members of the Medical Cannabidiol Advisory Board:

Two improvements to Iowa's medical cannabis program, both proposed in House File 732, are the focus of your discussion today, and we respectfully submit these comments for your consideration. These improvements will help ensure patients can finally receive cost-effective medicine, in forms that address their needs. As we detail below, the 3% formulation cap must be replaced by a purchase cap on THC, and that purchase cap must adequately address Iowans' needs. HF 732 proposes both of those improvements, and we strongly urge you to recommend that the Iowa Legislature support this bill.

MedPharm Iowa is more than just the state's first licensed manufacturer and dispensary; we are advocates for the patients we serve. In all that we do, we are guided by our mission of improving our patients' lives. We believe it is paramount that we amplify the voice of our patients, who should be at the center of the decisions made surrounding the operation of Iowa's medical cannabis program. Remember why this law was passed in the first place: to compassionately provide suffering Iowans with another option for seeking relief from pain, seizures, and other debilitating conditions.

These patients shouldn't have to wait longer for the relief they deserve, and HF 732 will help deliver relief for thousands of suffering Iowans.

The 3% formulation cap must be replaced with a purchase cap on THC.

The 3% formulation cap must be replaced with a purchase cap on THC. Iowa's formulation cap unnecessarily increases the cost of the medicine and limits patients' ability to treat their conditions effectively – all while failing to prevent diversion and abuse. Replacing the formulation cap with a purchase cap on THC, however, allows patients access to the dose and form they need, and it allows dispensaries and the state to better prevent diversion and abuse.

Why is the 3% formulation cap so costly? Let's use capsules, which have been among the most popular products to date, as an example. Currently, manufacturers are forced to use larger capsules and add more filler to capsules to make sure they comply with the 3% formulation cap. Though not providing any benefit to patients, this process introduces additional cost to patients, as it necessitates more expensive product material, labor, and larger packaging. Those costs are passed onto Iowans while providing no discernable benefit. These much larger capsules have also presented problems for patients who have trouble swallowing.

We've spoken to more than two hundred patients who have cited the high cost as the reason for not making subsequent purchases. We've spoken to dozens of patients who have told us they need a higher dose to receive the relief they're seeking, but they simply can't get there because they

can't afford it. **This cap has real effects for patients, and it is incumbent on all of us to address the concern.**

As part of this discussion, it is important to establish dosing ranges for various conditions approved in Iowa. Below is a table compiled from **actual** patient data from Minnesota¹, which is a very similar program to Iowa.

Minnesota Daily Doses across Conditions			
Condition	Average daily dose THC (mg)		
	Low	Average	High
Intractable Pain	20	60	550
Severe and persistent muscle spasms	15	82	1400
Cancer	20	80	700
Seizure disorder	10	75	275
Crohn's	15	70	300
Terminal Illness	20	50	3000
HIV	15	90	135
ALS	15	40	205
Average across Conditions	15	70 mg THC	820

MedPharm Iowa serves several hundred patients in its two dispensaries, and it has instituted a research program for collecting similar data. During the first four months of operation, average daily doses for our patients appear to be quite similar to Minnesota. **Nearly 40% of the current patient base in our two dispensaries average more than 80 mg of THC per day.**

This Board also rightly recognized the need for fast-acting relief for certain patients suffering from acute pain, relief that could be provided through vaporization. Patients were thankful that the Board continued to fight for vaporization, and earlier this year that fight ended successfully, with the addition of vaporization as a permitted form.

Unfortunately, the 3% formulation cap will effectively prevent formulation of vaporizable products with THC, which will make these products ineffective for patients who need this form. A standard 500 milligram vaporization cartridge subject to the 3% formulation cap would permit up to 15 milligrams of THC *in the entire cartridge*. Using the average patient from Minnesota as an example, a patient would need to purchase and consume more than four cartridges *per day*, which would require this patient to take more than 900 inhalations *per day*. While surely the Board did not intend this, it is the reality of formulating vaporization products with a 3% cap.

¹ See Minnesota Medical Cannabis Program: Patient Experiences from the First Program Year (<http://www.idph.iowa.gov/Portals/1/userfiles/234/Files/First%20Year%20Report.pdf>) and Intractable Pain Patients in Minnesota Medical Cannabis Program: Experience of Enrollees During the First Five Months (<http://www.idph.iowa.gov/Portals/1/userfiles/234/Files/MN%20Intractable%20Pain%20report.pdf>)

Costs of the 3% Cap				
Example: 70 mg THC/day				
Form	Total mg THC per Cartridge	Cartridges Needed/Day	Dose Per Inhalation	Daily Inhalations Needed
3% Capped Cartridge	15	4.6	0.075 mg THC	933
Standard Cartridge	500	< ¼ of one cartridge	2.5 mg THC	28

Simply put, this formulation cap hurts patients by increasing costs and preventing patients from using certain approved forms.

We've been told that if the formulation cap is removed, the medicine will become more potent. This statement perhaps best illustrates the confusion this cap has caused. Let's consider our capsules, this time using the 10 milligram capsules. Recall that we are measuring potency by weight of the active ingredient (THC) divided the total weight of the capsule.

With a 3% formulation cap, and 10 milligrams of THC serving as the active ingredient, the total weight of the capsule must be at least 300 milligrams ($10/300 = 3\%$ THC). With the formulation cap replaced, we can put that exact same 10 milligrams of THC into a much smaller capsule, such as a 100-milligram capsule. Although the "potency" has increased as calculated ($10/100 = 10\%$ THC), **the actual milligrams of THC have not changed**. It is simply now available in a smaller capsule that is much easier to consume and requires less filler and less labor to create. This is why medicine is not measured in percentages, because a percentage does not tell the full story. Remember, regardless of the cap, a patient's dose does not change; this is instead a question of how we effectively provide those doses to patients.

Finally, the formulation cap limits the individual products, as noted, but it does not adequately prevent a patient from buying a nearly unlimited amount of THC. We support a purchase cap, though, because it allows patients to purchase the individual products they need while preventing a patient from buying too much THC – thereby helping to prevent diversion and abuse.

The purchase cap on THC proposed in House File 732 is currently adequate for Iowa.

While we understand that setting an appropriate limit on the amount of THC that may be purchased in a 90-day supply is challenging, we believe addressing patient needs should guide that decision. The Iowa House's proposal of 25 grams over 90 days provides an adequate supply for the large majority of patients, and the waiver process will address the needs of those patients who may need more in certain limited circumstances.

One good source of information is to examine other states. While Minnesota does not currently have a purchase cap, the average of the top doses is 820 milligrams per day, or 74 grams over 90 days. Setting a cap of 74 grams over 90 days would thus cover more than 95% of Minnesota patients. Purchase caps in other states' medical programs are illustrated below, extrapolated to 90

days for ease of comparison. Note that in other states, caps range from 14-day or 30-day, while other state set possession limits. Other states do not have a purchase cap on THC.

State / Country	Grams THC / 90 days
Connecticut, New Mexico	42
District of Columbia	68
Minnesota (if based on patient data)	74
Maine, Massachusetts, Maryland, Arizona, Arkansas, Illinois, Israel, Nevada, Rhode Island, Delaware	90
Germany, Alaska, Montana, Oregon	300-500
Colorado, New Hampshire, Vermont, Michigan, Oklahoma, Washington, Hawaii	1,000-2,000
California	2,000+
Minnesota (actual), New York, Pennsylvania	No limit

What's happening in Iowa? In our dispensaries, we have patients taking 40 milligrams of THC 4-5 times daily to control chronic pain. We have patients taking 150 milligrams of THC per day, spread out across a full day of chemotherapy treatments. We have patients suffering from stage 4 cancer taking 240 or more milligrams per day. In short, we have patients in severe pain, who are dealing with serious, debilitating conditions. These are the patients a purchase cap must consider.

We understand that there is an idea that a 7.5 gram / 90-day purchase limit would be sufficient, but this is simply untrue. Apparently, this figure comes from a review of literature performed *before* Minnesota's program launched. Although literature can absolutely help guide decision making, it should not be the only consideration – especially when actual patient data exists in our state and in states with programs similar to ours. Among the flaws of relying solely on that Minnesota review, we stress that it included groups of patients who had their doses proscribed by researchers, and patients were not allowed to choose or increase their doses.

How would a 7.5-gram cap affect Iowans? At least a third of our patients in each of our dispensaries would immediately have to reduce their doses, because they wouldn't be permitted to purchase the supply they need. **These are real people seeing real benefits from cannabis that would no longer be served by this program, through no fault of their own. Telling hundreds of patients who are otherwise receiving relief, often for the first time in years, that they must cut their dose for no discernable reason would be simply cruel.**

Although not perfect, we do believe that as the current program stands, the proposed 25-gram purchase cap will adequately serve at least 90% of Iowa patients, and we believe the waiver process will address those limited circumstances where patients may need more THC to combat their symptoms or pain.

Thank you for your consideration. We urge you to support House File 732, for all Iowans who may benefit from medical cannabis.