2019 Annual Report

Iowa Medical Cannabidiol Board – Annual Report to the Iowa General Assembly

Authorship – Division of Behavioral Health, Office of Medical Cannabidiol

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Iowa Department of Public Health

Protecting and Improving the Health of Iowans

Acknowledgements

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Iowa Medical Cannabidiol Board Members – Cpt. Mike McKelvey, Chair, Dr. Ken Cheyne, Dr. Jill Liesveld, Dr. Lonny Miller, Dr. Stephen Richards, Dr. Robert Shreck, and Dr. Jacqueline Stoken.

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Executive Summary

Iowa Code chapter 124E was enacted on May 12, 2017. This code chapter established the Medical Cannabidiol Board (Board). The Board is tasked with the following responsibilities[1]:

1. Accepting and reviewing petitions to add medical conditions, medical treatments or debilitating diseases to the list of debilitating medical conditions for which the medical use of cannabidiol would be medically beneficial under this chapter.
2. Making recommendations relating to the removal or addition of debilitating medical conditions to the list of allowable debilitating medical conditions for which the medical use of cannabidiol under this chapter would be medically beneficial.
3. Working with the department regarding the requirements for the licensure of medical cannabidiol manufacturers and medical cannabidiol dispensaries, including licensure procedures.
4. Advising the department regarding the location of medical cannabidiol manufacturers and medical cannabidiol dispensaries throughout the state.
5. Making recommendations related to the form and quantity of allowable medical uses of cannabidiol.
6. The Board also has the authority to make a recommendation for a statutory revision to the definition of medical cannabidiol to increase the allowable tetrahydrocannabinol (THC) level in medical cannabidiol products manufactured and sold in the state of Iowa[2].

This report summarizes the Board's activities and recommendations for improvement in each of these areas during calendar year 2019.

Just 18 months after the Medical Cannabidiol Act was signed into law, the first Iowan obtained medical cannabidiol that was legally manufactured and dispensed within Iowa. The Office of Medical Cannabidiol (OMC) continues to oversee registration of patients and caregivers, as well as the manufacture and sale of medical cannabidiol products to ensure they are dispensed in a manner that protects public health and safety. Calendar year 2019 has seen the combined number of patient and caregivers approved by IDPH increase by more than 600% and product sales exceed $2,200,000. The data within the following figures and tables for this report were obtained through December 15, 2019, from the OMC Patient Registry and Secure Sales and Inventory Tracking System.

The Board recommendations highlighted in this report are aimed at improving Iowa's Medical Cannabidiol Program, which employs high quality manufacturing and quality assurance standards, in a manner that strives to protect public health and safety.

[1] Iowa Code section 124E.5(3)
[2] Iowa Code section 124E.5(6)

I. Report on Activities of the Board

Board Meetings[3]

The Board held four meetings during 2019 as allowed by Iowa Code chapter 124E.

1. February 1, 2019
2. April 16, 2019
3. August 2, 2019
4. November 1, 2019

February 1, 2019

At its February meeting, the Board considered two petitions for the addition of new qualifying conditions:

1. Cortico-basal Degeneration – **Approved (unanimously)**
2. Pulmonary Hypertension/Right-Heart Failure – **Denied (unanimously)**

The Board received a presentation by Dr. Ed Gogek, a psychiatrist, on the negative impacts of THC on the brain. Owen Parker, program manager, gave a presentation on the status of medical card registrations and sales. The Board also received an update on modifications to the facility and timeline on Iowa's second licensed manufacturer, Iowa Relief, as well as updates from Iowa's other licensees.

April 16, 2019

This meeting was originally scheduled for May, but was moved to April at the Board's request to provide the Board with an opportunity to discuss pending legislation related to the program. At its April meeting, the Board considered two petitions for the addition of new qualifying conditions:

1. Severe, Intractable Autism with Self-Injurious or Aggressive Behaviors, All Ages
2. Adult Autism with Aggression and/or Self-Injury
    - The Board moved to combine the above petitions and considered the addition of "Severe, Intractable Autism with Self-Injurious or Aggressive Behaviors" – **Approved (unanimously)**

The Board also reviewed a letter from the Podiatric Medical Society, and considered making a recommendation to add podiatrists to the list of healthcare practitioners eligible to complete patient certifications for participation in the program. This recommendation was denied by a 4-1 vote.

The Board discussed the purchase cap of 25g THC per 90 days as proposed by 2019 Iowa Acts, House File 732. While the Board was in favor of the elimination of the **3%** THC cap, they

[3] Iowa Code section 124E.5(2)

recommended a lower purchase cap of **4.5g** THC per 90 days, which was approved unanimously.

August 2, 2019

At its August meeting, the Board considered five petitions for the addition of new qualifying conditions:

1. Generalized Anxiety Disorder – **Denied (unanimously)**
2. PTSD – **Deferred to November 1, 2019 meeting**
3. Schizophrenia, Personality Disorder, Rape Trauma, Social Phobia, etc. – **Denied (unanimously)**
4. Opioid Dependency, Tolerance, & Use Disorder – **Denied (6-1)**
5. Severe or Chronic Pain – Amended to "Chronic Pain" – **Approved (unanimously)**

The Board considered a petition to recommend that the Department of Public Health ask the federal DEA to recognize Iowa's Medical Cannabidiol Program as exempt from federal drug laws, which the Board approved.

The Board received a presentation from Owen Parker, program manager, on updated program data and how access to THC in Iowa compares to other states.

The Board received a presentation from the Iowa Podiatric Medical Society recommending the addition of podiatrists to the list of healthcare practitioners eligible to complete patient certifications for participation in the Iowa program. The Board approved the recommendation by a 6-1 vote.

There was a motion to assemble a Medical Cannabidiol Petition Subcommittee of the Board (three members) to review petitions and make recommendations to the full Board, and the motion was approved.

The Board's recommendations to be included in the Annual Report were discussed, and are included in Section II of this document.

November 1, 2019

At its November meeting, the Board considered four petitions for the addition of new qualifying conditions:

1. PTSD – **Approved (4-2)**
2. Intellectual Disability (ID) with Aggression and/or Self-Injury – **Approved (5-1)**
3. Opioid Dependency, Tolerance, & Use Disorder – **Denied (Unanimously)**
4. Alzheimer's Disease – **Denied (Unanimously)**

At 8:30 a.m. on November 1, the recently assembled Medical Cannabidiol Petition Subcommittee received public comment on the petitions above. This subcommittee was assigned to review the petitions to add new conditions, including the literature included with and referenced within the petitions. The subcommittee also did independent research for additional literature regarding the use of medical cannabis to treat the petitioned conditions,

and was allowed to make recommendations to the full Board related to a decision on the petition. This subcommittee of the Board is currently comprised of Drs. Shreck, Richards and Liesveld.

The Board considered an additional petition for the addition of vaporized flower as a new medical treatment; however, this would be in conflict with Iowa Code 124E which forbids "combustible" form and no action was taken on this petition.

The Board received updates from licensees on their operations, a review of data from the first year of sales from Owen Parker, and the results of a survey done by the College of Public Health at the University of Iowa on Iowa physicians about their attitudes and knowledge around medical cannabis.

The Board also further discussed their recommendations to be included in this report and these are included in Section II of this document.

In Summary:

As detailed above, the Board considered petitions to add 11 new qualifying debilitating medical conditions during 2019.

1. Cortico-basal Degeneration
2. Pulmonary Hypertension/Right-Heart Failure
3. Severe, Intractable Autism with Self-Injurious or Aggressive Behaviors, All Ages
4. Adult Autism with Aggression and/or Self-Injury
5. Generalized Anxiety Disorder
6. PTSD
7. Opioid Dependency, Tolerance, & Use Disorder
8. Schizophrenia, Personality Disorder, Rape Trauma, Social Phobia, etc.
9. Severe or Chronic Pain
10. Intellectual Disability (ID) with Aggression and/or Self-Injury
11. Alzheimer's Disease

The Board recommended adding the following debilitating medical conditions in 2019[4]:

1. Cortico-basal Degeneration – Approved by the Board of Medicine (Effective October 16, 2019)
2. Severe, Intractable Autism with Self-Injurious or Aggressive Behaviors – Approved by the Board of Medicine (Effective November 27, 2019)
3. Chronic Pain – Unanimously denied by the Board of Medicine on September 20, 2019
4. PTSD – To be considered by the Iowa Board of Medicine
5. Intellectual Disability (ID) with Aggression and/or Self-Injury – To be considered by the Board of Medicine

II. 2019 Recommendations of the Board to the Iowa General Assembly

Please note: The Board has authorized its chairman to appoint, from time-to-time, one to three Board members to meet with other stakeholders to discuss and explain the recommendations below.

1. Removal of the 3% THC Limit in Final Medical Cannabidiol Product Formulations, and Movement to "4.5g THC per 90 days"[4]

The Board recommends removal of the **3%** THC limit in medical cannabidiol product formulations and replacement with a purchase limit of **4.5g** THC per 90 days. This recommendation was made at the April meeting and re-affirmed at the August meeting.

Rationale: The current **3%** THC limit does not allow for effective tincture or vaporizable forms, both of which enable more precise dosing by the patient. The current medical literature reviewed by the Board provides convincing evidence of benefit from medical cannabis for various conditions with THC doses up to **30 milligrams (mg)** per day (which is **2.7 grams (g)** of THC per 90-day period). The Board recommends a limit of **4.5g** THC per 90 days (which is **50mg** THC per day) as a compassionate effort to cover outliers as a result of variable body size, body metabolism, inefficient application, etc. This recommended purchase cap of **4.5g** THC per 90 days is in recognition of the limited intent of the Iowa program.

The Board does recommend two exceptions to this purchase cap of **4.5g** THC per 90 days, both involving active intervention, management and judgement by the patient's certifying healthcare practitioner:

- **a.** The Board recommends allowing certifying health care practitioners to waive the **4.5g** THC per 90 days purchase limit for patients who are certified to be terminally ill with an estimated survival of less than one year.
- **b.** The Board recommends that certifying health care practitioners be able to certify any other patients for a higher THC purchase limit if, after participating in the program under the **4.5g** THC purchase limit, the patient and certifying health care provider agree that **4.5g** of THC over 90 days is not a sufficient amount of THC to treat the patient's debilitating medical condition.

2. Removal of the Felony Disqualifiers for Patients and Caregivers

Currently, chapter 124E disqualifies patients and caregivers with certain felony convictions from obtaining a registration card. The Board recommends removing this provision, as withholding medical treatment on the basis of criminal conviction violates the *AMA Code of Medical Ethics*.

[4] Iowa Code section 124E.5(6)

3. Adding Mid-level Providers to the List of Healthcare Practitioners

Chapter 124E permits only licensed physicians to certify a patient's debilitating medical condition for purposes of obtaining a patient or primary caregiver registration card. To ensure access to registration cards for a greater number of patients, the Board recommends allowing advanced practice providers, including physician assistants (PAs), advanced registered nurse practitioners (ARNPs), as well as podiatric physicians to certify a patient's debilitating medical condition for the purpose of obtaining a medical cannabidiol registration card. These practitioners have prescribing authority under both Iowa and Federal law identical to that of MDs and DOs, and currently provide a significant fraction of primary care in Iowa.

4. Require Pharmacists in Dispensaries

The Board recommends requiring pharmacists in dispensaries to make dosing recommendations. The Board makes this recommendation to ensure patient safety. At least two other states, Pennsylvania and Minnesota, require a licensed pharmacist to work at each dispensary.

5. Physician Access to the Patient Registry

The Board recommends adding an exception to the confidentiality provisions for the patient registry established by Chapter 124E for licensed medical providers that are permitted to certify patients for participation in the program. This would allow providers to determine whether patients have been approved for medical cannabidiol registration cards by providers other than themselves. This could be done through a validated request directly to the Secure Sales and Inventory Tracking System.

6. Develop Language to Protect Schools, and Long-Term and Acute Care Facilities

Facilities that receive federal funding are hesitant to allow medical cannabidiol products to be administered and stored at the facilities due to the current scheduling of *Cannabis* at the federal level. There are Iowa patients within these facilities who are unable to store their medication at the facility, or have their medication administered by facility staff, because of concerns about adverse consequences for the facilities. Developing language to protect these facilities or seeking exemption for Iowa's program from federal drug laws would benefit patients and facilities.

7. Require Department Research (Observational Study)

The Board recommends that the department have the authority and resources to conduct an observational effectiveness study with patients and healthcare practitioners, as there is limited domestic research on the effectiveness of medical cannabidiol products. This would be similar to Minnesota's program, which receives resources to conduct ongoing observational studies with their patients and providers.

8. Movement to a "Total THC" Calculation for Determination of Product Potency

Currently, chapter 124E only takes Tetrahydrocannabinol (THC) into account when calculating the THC content for products. It does not take Tetrahydrocannabinolic Acid (THCa) into account - THCa converts to THC when heat is applied. The Board recommends moving to a "total THC" formula including both THC and THCa for determining THC purchase limits, so that the total effective THC in a product can be considered. This is typically the way THC content is measured in other state-regulated cannabis programs.

9. Removal of the Department of Transportation (DOT) from the Registration Card Process

The current requirement to obtain a registration card from the DOT is a barrier to access. The Board acknowledged that this requirement does not prevent fraud because patients and caregivers are required to provide proof of identification at the time of application for a registration card, and the validity of the identification provided is verified by the Department of Public Health, using DOT data, at the time of patient registration. The Board recommends IDPH issue patient and caregiver registration cards directly to eliminate the burden on sick patients to go to the DOT to get a registration card.

10. Renaming the Program to Reflect the Comprehensive Nature of the Program

The Board recommends renaming Chapter 124E to be the "Iowa Medical Cannabis Act" to reflect that products containing THC are also authorized to be sold and manufactured by the law.

11. Board Meeting Frequency

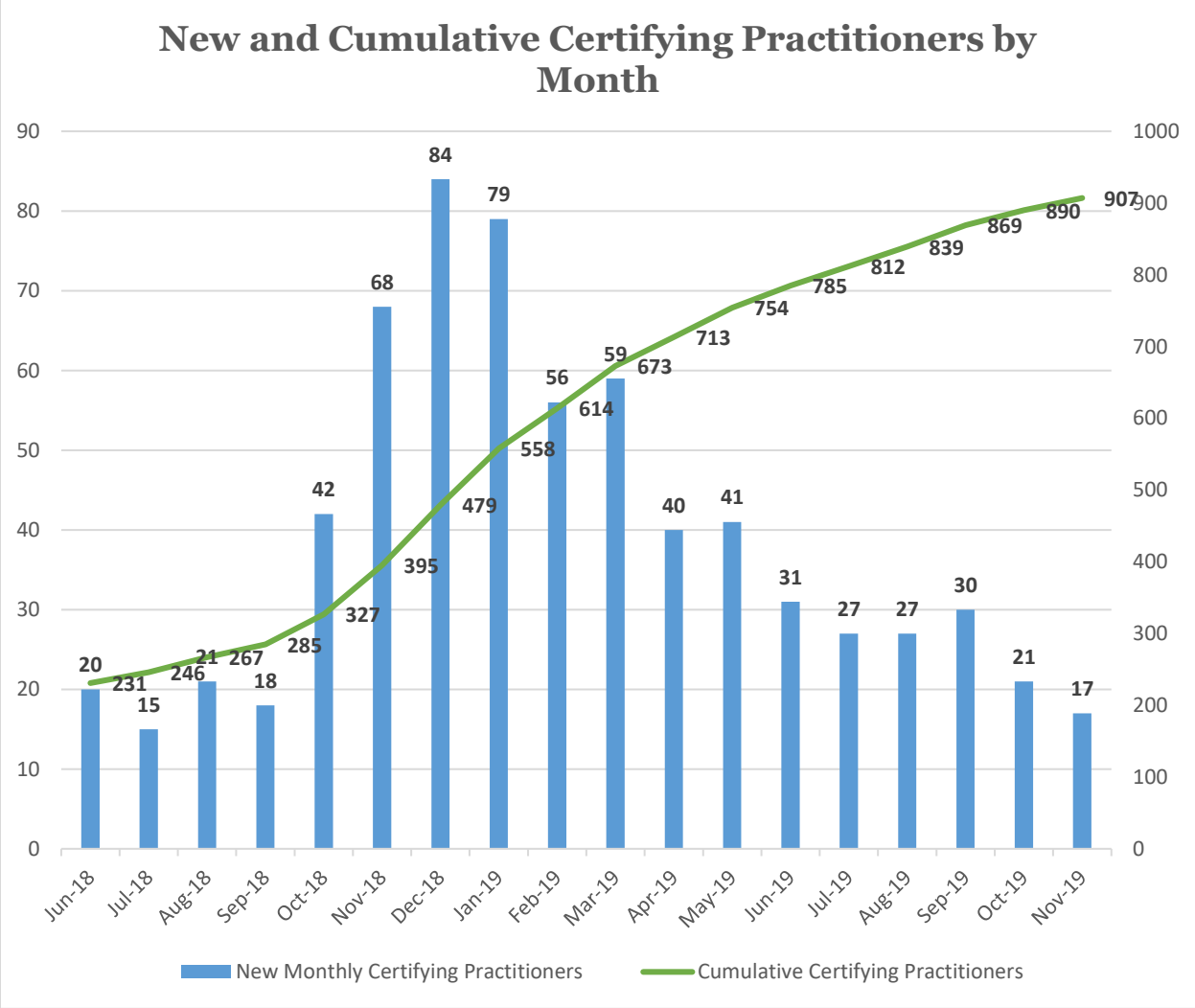
The law currently restricts the number of board meetings to four per year. Board members would like to see that restriction lifted. The intent would be to still meet quarterly, but it would be helpful to have the ability to meet more frequently, should the need arise.

III. Data from Year-One of Program Sales

1. Healthcare Practitioner Certification

To issue a certification for the use of medical cannabidiol to patients, there is no requirement for a physician to complete specific training on medical cannabis. Although it is a recommendation of the Board to allow additional disciplines to certify patients, at this time it is limited to physicians only. Early on in the program, physician engagement was limited. **Figure 1** depicts how, throughout the first year of sales (beginning December, 2018), there has been a progressive increase in the overall participation from Iowa's physicians. Over the past 18 months, OMC staff gave over 60 educational presentations across the state to physicians and healthcare stakeholders. There are over 900 unique Iowa physicians who have certified at least one patient, a greater than 160% increase since program sales began on December 1, 2018.

Figure 1.



2. Patient Registration and Demographics

Prior to the availability of in-state manufacturing and dispensing of medical cannabidiol products, patient participation in the program was limited. Since sales began December 1, 2018, there has been a greater than 600% increase in the number of approved patients. **Figure 2** depicts the monthly and cumulative number of patient approvals since January 2018. Since program sales launched (December 2018), the department has received 300-450 applications per month. Entering the second year of product sales, IDPH will closely monitor data on patients renewing their registrations.

Figure 2.

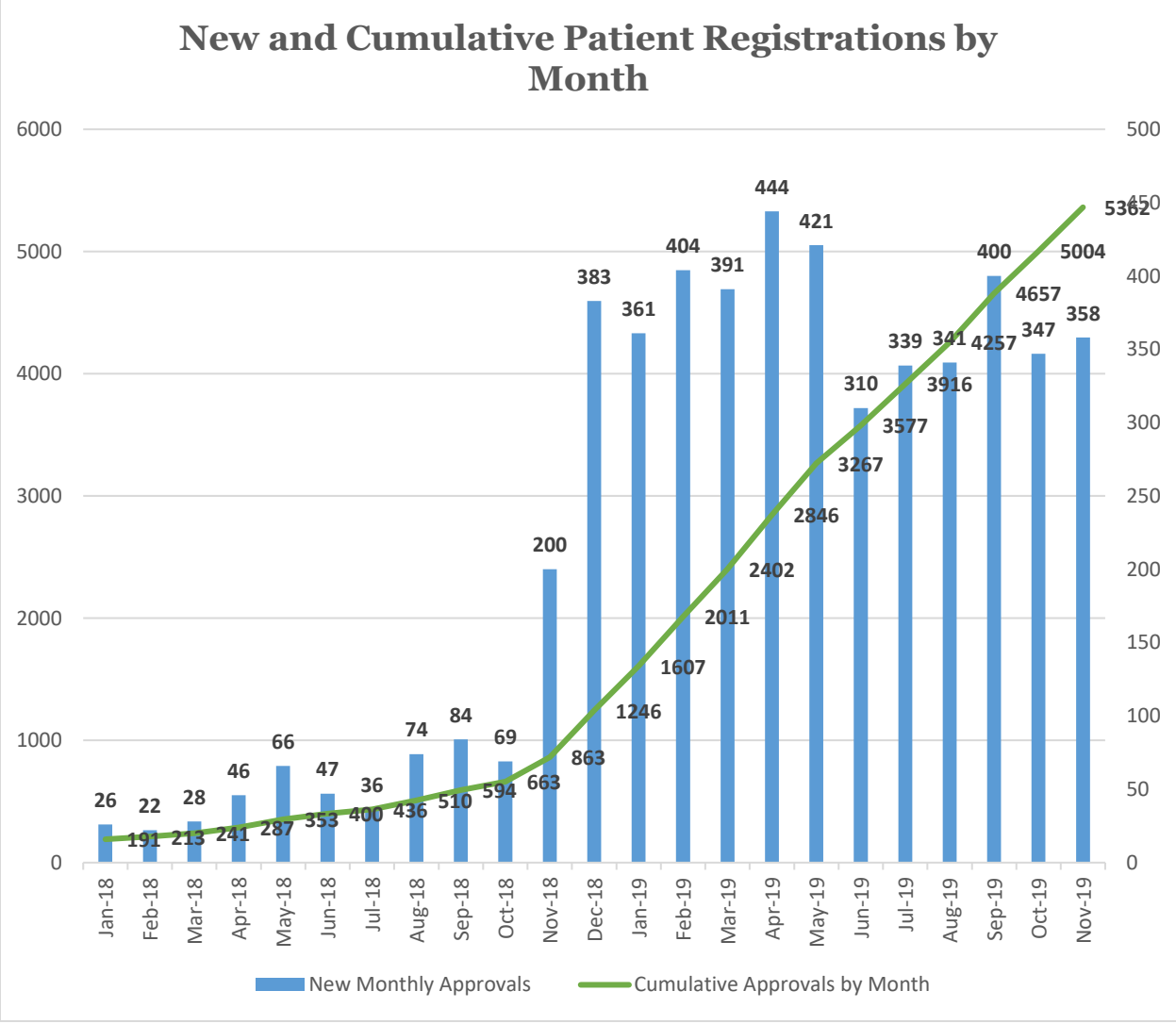
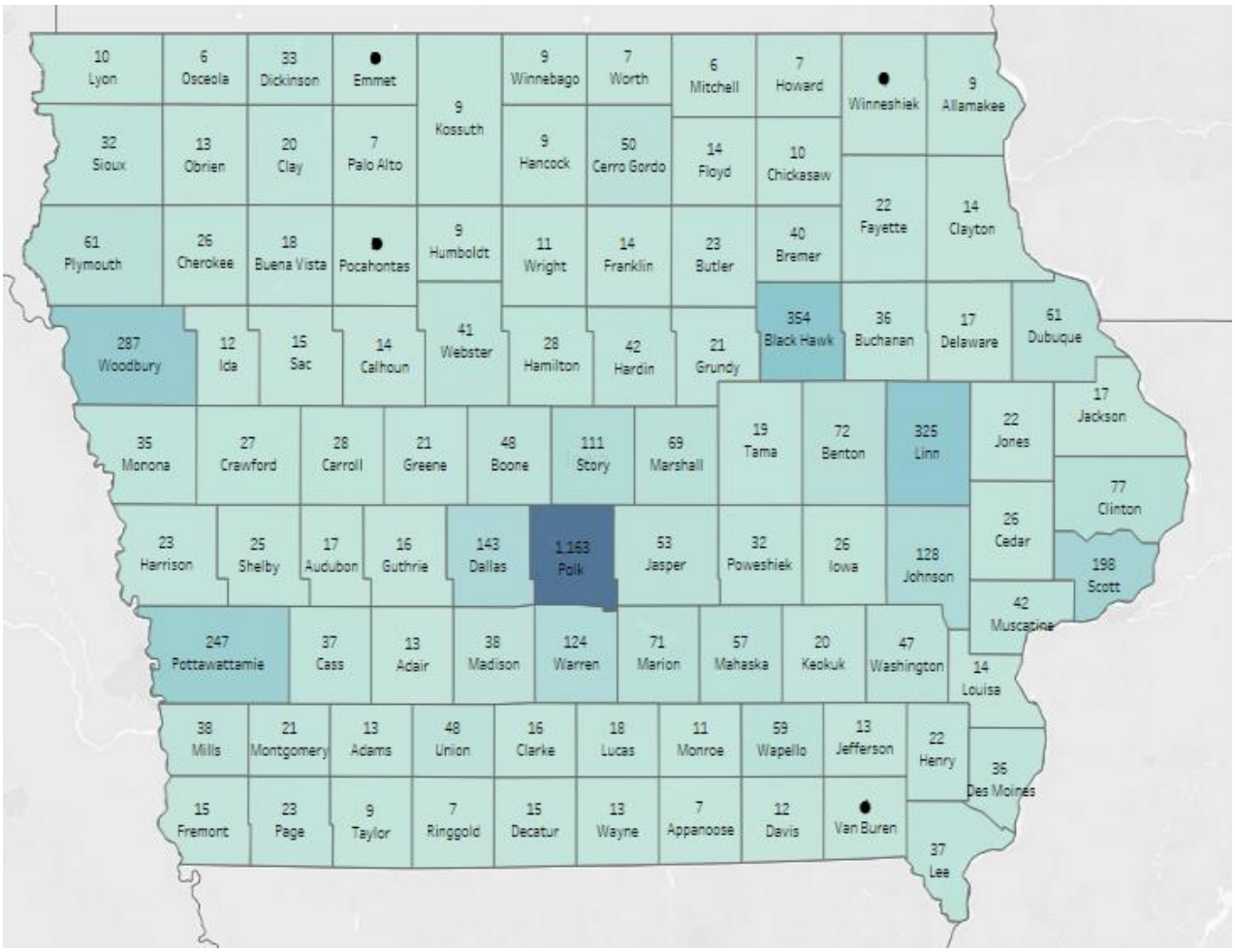


Figure 3 depicts the patient population density of all of Iowa's counties. The vast majority of patients are concentrated in urban areas, as well as communities that contain one of the five licensed dispensaries. There has been limited participation in Iowa's more rural communities. This could be attributed to multiple factors, including, but not limited to, only having a single primary care provider who may or may not complete a patient certification, as well as distance to the nearest dispensary.

Figure 3.

Patient Population Density by County



*Note: Values of < 5 are indicated by **

Table 1 depicts the patient certification by age group for each qualifying condition. To date, the most common certified qualifying condition is untreatable pain (66.83%). In relation to gender, there is near-equal participation in the program between males (47%) and females (53%). Additionally, nearly 50% of the program's patient population are between the ages of 50 and 70 years.

Table 1.

Patient Certifications by Age and Qualifying Condition

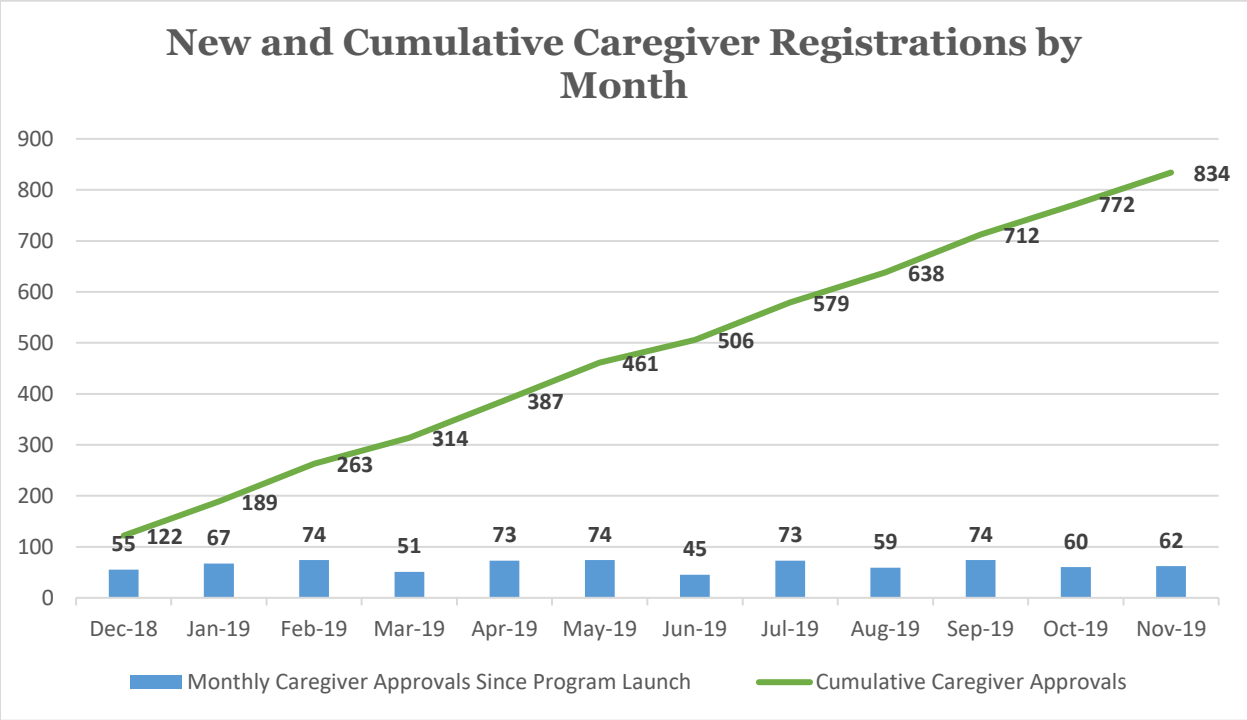
Age Range	AIDS/HIV	ALS	Autism	Cancer	Crohn's	MS	Parkinson's	Seizures	Terminal	Ulcerative Colitis	Untreatable Pain	Total	% age range
1-10				2		2		19	1		2	26	0.56%
11-20			14	4	2	1	1	28	0		13	63	1.36%
21-30	2		11	7	18	7	1	38	1	6	116	207	4.47%
31-40	9		6	26	28	36		35	4	11	313	468	10.11%
41-50	6			53	32	72	8	39	3	5	484	702	15.17%
51-60	14	2		121	20	103	21	25	4	5	774	1089	23.53%
61-70	7	11		170	20	57	60	19	9	4	762	1119	24.18%
71-80		10		111	10	14	67	3	12		427	654	14.13%
81-90		1		31		2	43	1	5		177	260	5.62%
91-100				3			3		2		25	33	0.71%
Total	**38**	**24**	**31**	**528**	**129**	**306**	**207**	**200**	**41**	**31**	**3093**	**4628**	**100.00%**
%Total	0.82%	0.52%	0.67%	11.41%	2.79%	6.61%	4.47%	4.32%	0.89%	0.67%	66.83%	100.00%	

Note: Patients may have more than one qualifying condition; however, the data reflected in this table represents unique certified patients and includes only the primary condition listed on each certification

3. Caregiver Registration

Designated caregivers are those who are certified by a patient's healthcare practitioner to purchase, possess and administer medical cannabidiol products on behalf of a patient. A caregiver will be designated if a patient is too ill, immobilized or otherwise unable to visit a dispensary. **Figure 4** depicts the cumulative and monthly caregiver applications that have been approved. As Iowa's conditions list consists of debilitating conditions, around 15% of all patients designate a primary caregiver.

Figure 4.



4. Dispensary Transactions

Iowa's five licensed dispensaries must transmit their medical cannabidiol dispensing data to the state's Secure Sales and Inventory Tracking System on a real-time basis, and reconcile their inventory with the state's system every week**. Figure 5** depicts unique monthly patient visits, as well as cumulative monthly transactions between the five licensed dispensaries during the first year of product sales. As patient numbers have continued to climb, the number of patient visits and overall number of transactions have continued to increase together in a linear fashion. To date, we have seen over 16,000 transactions culminate to greater than $2,200,000 in sales, with an average transaction price of $136.

Figure 5.

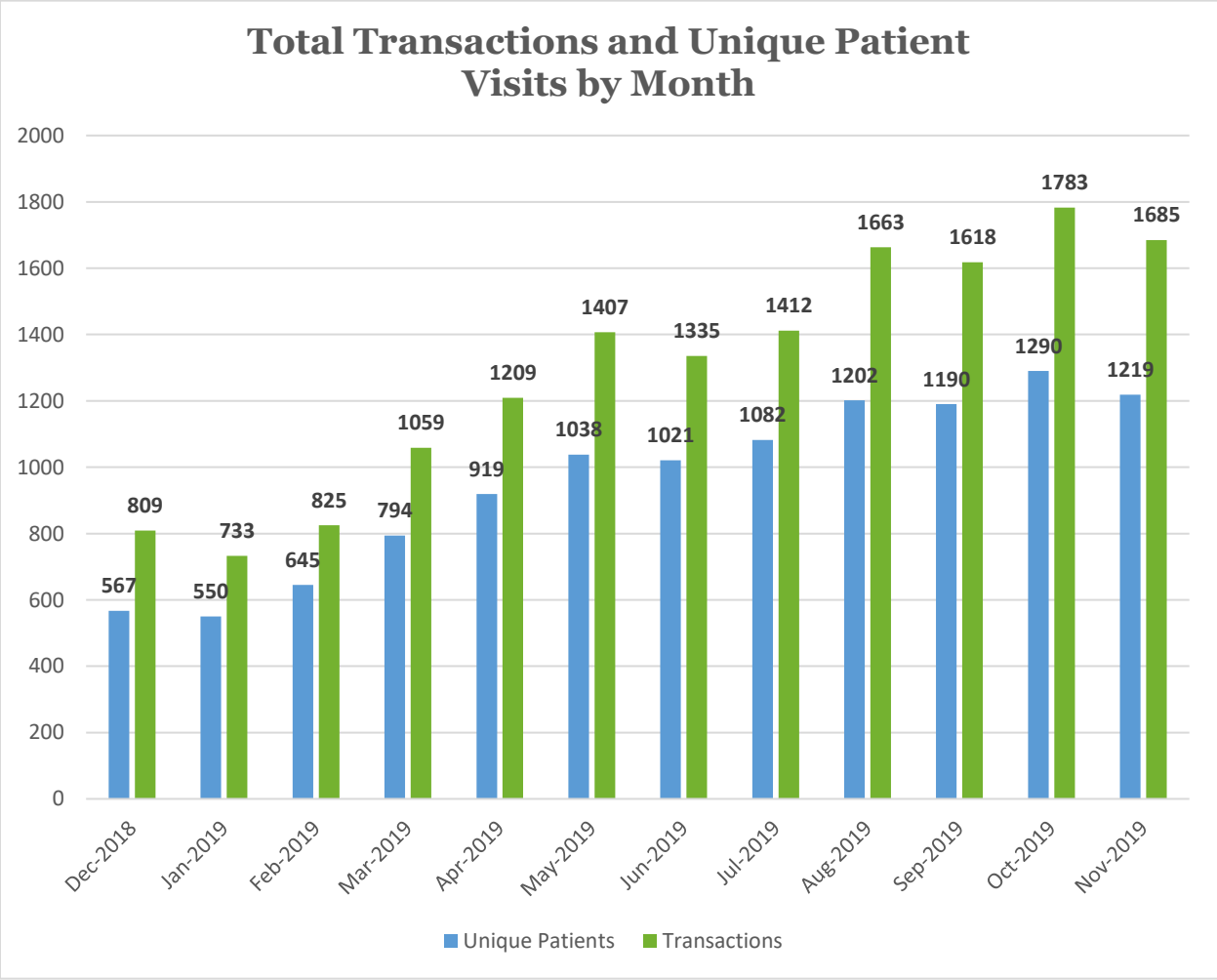
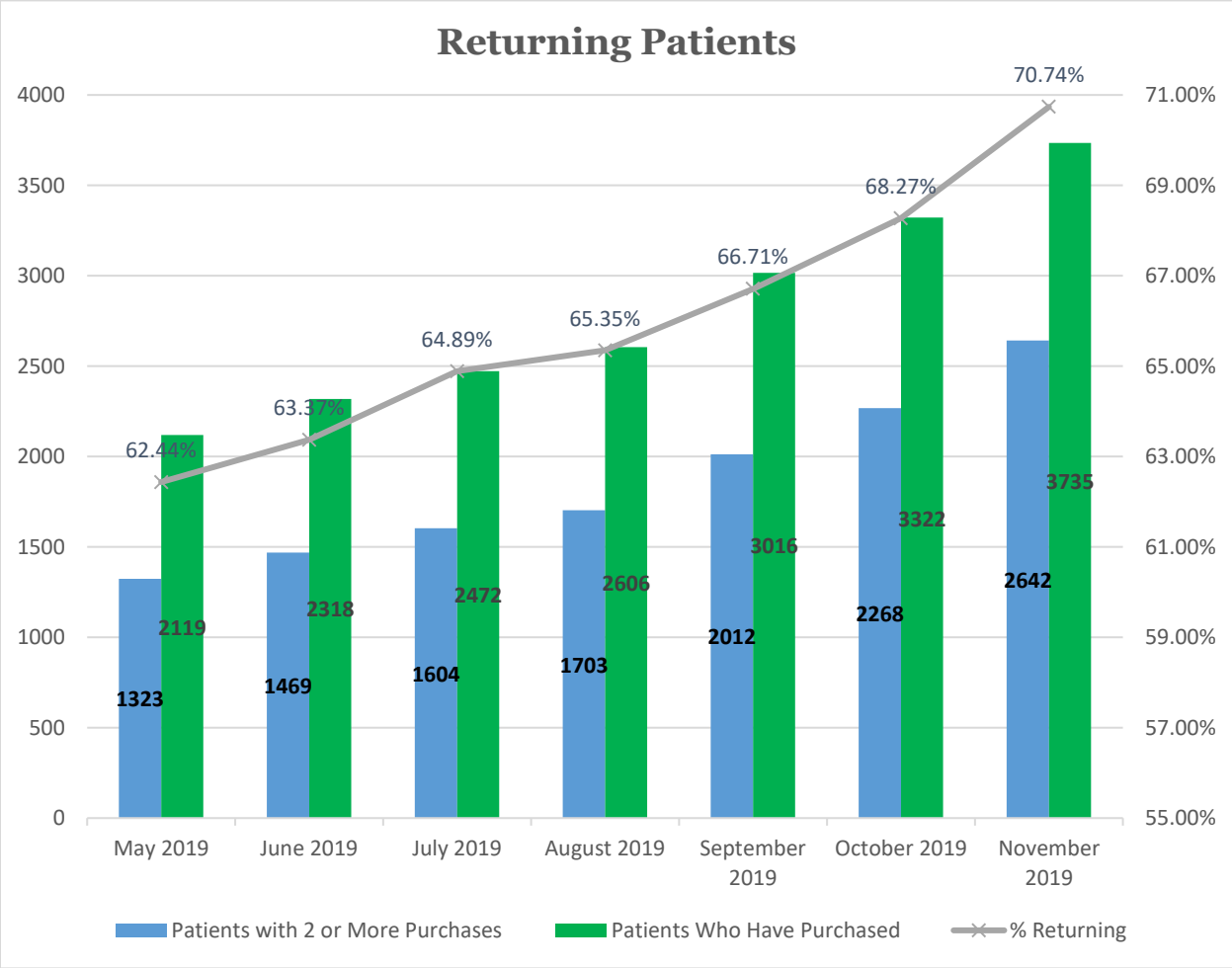


Figure 6 examines patient participation by comparing the number of patients who have made a dispensary purchase, to the percentage of patients who have made two or more purchases. Patients may only purchase once for a variety of reasons, including, but not limited to, product cost, product efficacy, death of the patient or distance from a dispensary. While Iowa has many patients who have only made a single purchase, the percentage of patients making multiple purchases has steadily increased.

Figure 6.



5. Purchasing Behavior by Form, Quantity, and Condition

Chapter 124E allows Iowa's two licensed manufacturers (MedPharm Iowa, LLC and Iowa Relief, LLC) to manufacture products in the following forms: oral forms (tinctures, capsules, tablets and sublingual forms), topical forms (gels, ointments, creams, lotions and transdermal patches), nebulizeable forms, suppositories and vaporized forms (vaporized forms became available for sale on August 7, 2019). None of the final product formulations have a Tetrahydrocannabinol (THC) greater than 3% in mg/g for solids, and mg/mL for liquids. Important to note, for most forms, a percentage-based potency calculation does not provide an actual limit on the amount of THC that can be contained in a product. **Figure 7** and **Figure 8** shows the overall percentage of product sales by formulation.

Figure 7.

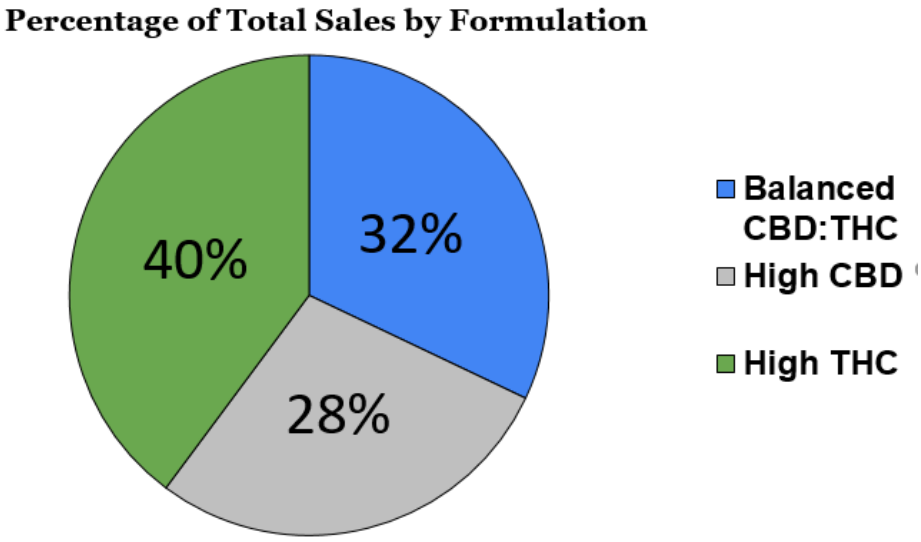


Figure 8.

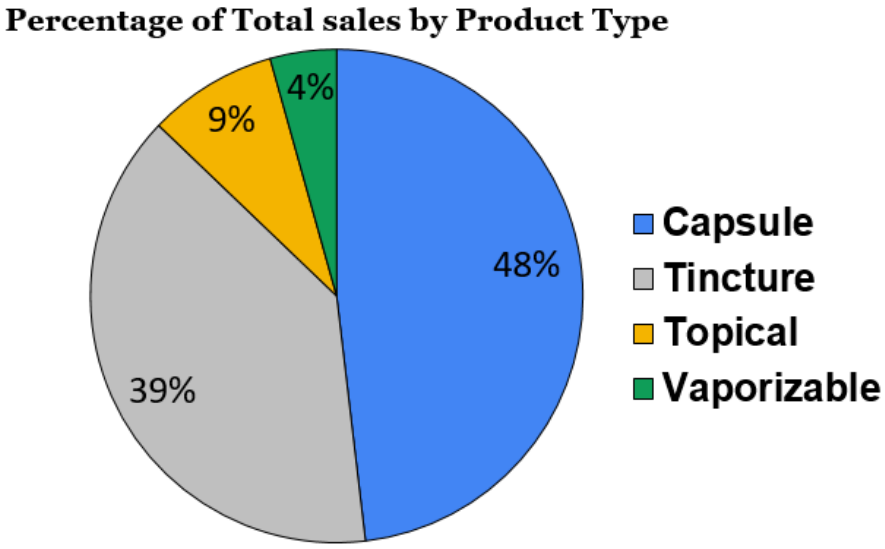
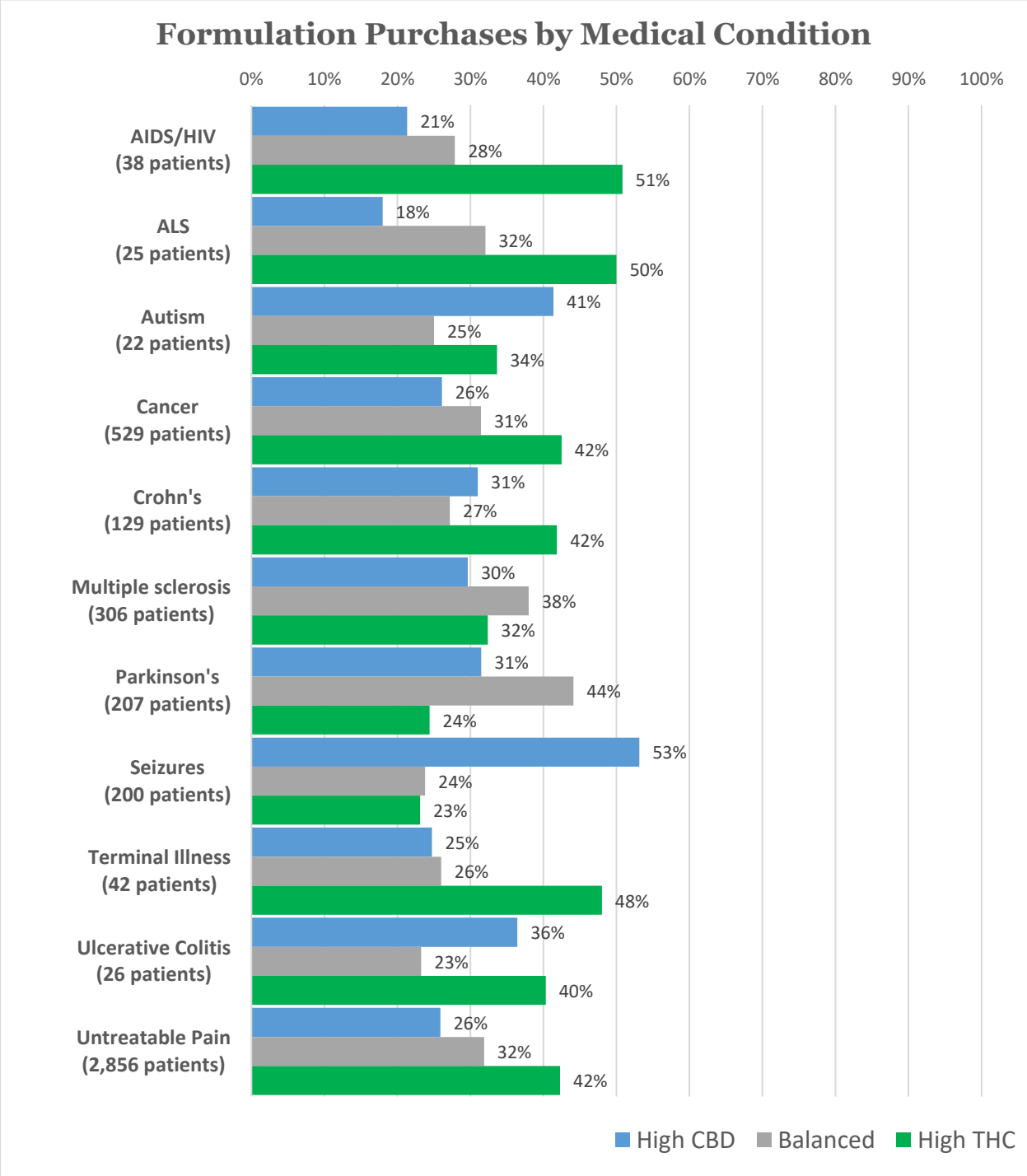


Table 2 provides percentage-based purchasing behaviors for a given product formulation and qualifying condition. Patients in Iowa purchase a variety of formulations of CBD and THC for a given condition.

Table 2.



IV. Product Testing & Adverse Event Reporting

Product safety and consistency is of paramount concern to the department. All medical cannabidiol products are tested by the University of Iowa's State Hygienic Laboratory (SHL). At the time of this publication, the department has not received any reports of adverse reactions or events related to products manufactured by our licensees.