STATE OF IOWA DEPARTMENT OF

Health AND Human SERVICES

Medical Cannabidiol Board

ANNUAL REPORT TO THE IOWA GENERAL ASSEMBLY

December, 2022

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Medical Cannabidiol Board

2022 ANNUAL REPORT TO THE IOWA GENERAL ASSEMBLY

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ACKNOWLEDGMENTS:

Iowa Medical Cannabidiol Board Members – Cpt. Mike McKelvey, Chair, Dr. Robert Shreck, Dr. Stephen Richards, Dr. Jacqueline Stoken, Dr. Andrea Weber, Dr. Michael Colburn, Dr. Mohamad Mokadem

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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. 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.

This report summarizes the Board's activities, recommendations for improvement, program highlights, and program data during calendar year 2022. The data within the following figures and tables for this report were obtained through December, 2022, from the BMC Patient Registry and Secure Sales and Inventory Tracking System. The Board recommendations highlighted in this report were developed to improve Iowa's Medical Cannabidiol Program.

The mission of the Bureau of Medical Cannabidiol (BMC) at the Iowa Department of Health and Human Services is to have a high-quality, effective, and compliant medical cannabidiol program for Iowa residents with qualifying medical conditions. The BMC works to balance a patient's need for access to treatment of their qualifying condition, while also ensuring the safety and quality of the products. The BMC oversees the registration of patients and caregivers, as well as the manufacture, testing, and dispensing of medical cannabidiol products. The BMC places focus on IT automation and quality improvement to meet program and stakeholder needs as volume increases, in order to meet these needs with limited expenditures and staffing.

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Report on Activities of the Board

I. BOARD MEETINGS

The Board held four meetings during calendar year 2022.

- February 11, 2022
- May 13, 2022
- August 12,2022
- November 18, 2022

FEBRUARY 11, 2022

At its February meeting, the Board did not consider any petitions for new qualifying conditions. Owen Parker, Bureau Chief, provided the Board a review of data from calendar year 2021. The Board welcomed two new members at the February meeting, Drs. Andrea Weber (psychiatry) and Michael Colburn (Pediatrics). AAG Heather Adams provided an overview to new and current Board members about their duties, and other legal considerations. The Board received an analysis of bills pertaining to the program, and well as administrative rule updates underway.

MAY 13, 2022

At its May meeting, the Board did not consider any petitions for new qualifying conditions. The Board heard comments from the public. The Board received an update on administrative rule updates, as well as a report of data for first five months of 2022.

AUGUST 12, 2022

At its August meeting, the Board did not consider any petitions for new qualifying conditions. The Board welcomed its new member for Gastroenterology, Dr. Mohamad Mokadem. The Board received a presentation on the mechanics and challenges of Iowa's Consumable Hemp Program from Mark Speltz and Tenesha Stubblefield of the Iowa Department of Inspections and Appeals. The Board heard updates from industry licensee representatives Lucas Nelson and Kevin O'Connor (Bud & Mary's Cannabis Co.) and Aaron Boshart (Iowa Cannabis Company). The Board had it's introductory conversation about recommendations for the 2022 Annual Report.

November 18, 2022

At its November meeting, the Board did not consider any petitions for new qualifying conditions. The Board heard a presentation from Kelly Flanagan at the DCI Crime Lab about testing challenges with consumable hemp products. The Board discussed telehealth certification, and ways for improving the patient-provider relationship. The Board discussed vaporizable flower as an allowed form and how other similar programs had implemented it. The Board finalized its recommendations for program improvement for its 2022 Annual Report.

II. MAKING RECOMMENDATIONS FOR ADDING OR REMOVING MEDICAL CONDITIONS

In the calendar year 2022, there were no petitions for new qualifying debilitating medical conditions submitted by the public for the Board's consideration.

III. 2022 RECOMMENDATIONS OF THE BOARD TO THE IOWA GENERAL ASSEMBLY

1. AMENDING THE NAME OF CHAPTER 124E TO "THE MEDICAL CANNABIS ACT"

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, reflect scientific reality via inclusion of all cannabinoids, mitigate confusion with program stakeholders, and improve program education.

The term "medical cannabidiol" may have been relevant prior to HF2589 and Iowa using a 3% THC limit on products, but Iowa is the only state using this nomenclature. As Iowa now allows product formulations similar to those in other medical cannabis programs, it is congruent with the rest of the country to update the name. Following the passage of HF2589, the maintenance of the term "medical cannabidiol" has progressively created a knowledge and communication barrier, and increasingly caused confusion with law enforcement, DHS investigation personnel, and healthcare stakeholders who are otherwise unaware that high-THC products are legally available in Iowa. This confusion has been exacerbated by the "*consumable hemp*" program, which provides OTC hemp-derived cannabinoid products.

2. ADDITIONAL MEDICAL CANNABIDIOL DISPENSARIES

The Board recommends that the Department be allowed to license dispensaries additional to that prescribed by Iowa Code chapter 124E, in an effort to provide Iowans with greater geographical access to medical cannabidiol products. Currently, chapter 124E limits the number of dispensaries to five. This could be accomplished by removing the prescribed number of licenses, and giving the Department authority to issue additional licenses based on evidenced-based demand analysis.

3. REMOVING SALES TAX FROM PATIENT PURCHASES AT A DISPENSARY

In an effort to reduce the cost burden of medical cannabidiol products on patients, the Board recommends that the sale of medical cannabidiol products be exempt from sales tax, as is the case for traditional prescribed medications. **Senate File 2157** was introduced in 2022 and provides a template pathway.

4. INCLUSION OF PAS AND/OR ARNPS IN THE MEDICAL CANNABIDIOL BOARD

In an effort to be inclusive of the disciplines allowed to certify patients for the use of medical cannabidiol, the Board recommends expanding the nine-member Board to allow PAs and ARNPs to be Board Members. The current licensure requirements for Board members are not afforded to PAs and ARNPs, therefore, Chapter 124E would need to be amended to allow dedicated seats for a PA and/or ARNP.

5. IOWA TAX STATUS: LICENSEE EQUALITY WITH TRADITIONAL BUSINESSES

In an effort to reduce the tax burden placed on plant-touching cannabis operators, the Board recommends decoupling Iowa's tax code from Section 280E of the federal tax code for individual and corporate tax purposes. Iowa's tax code "couples" or matches the federal tax code unless the state actively decouples it. **Senate File 2157** was introduced in 2022 and provides a template pathway.

6. PROVIDE A MECHANISM FOR CERTIFYING PRACTITIONERS TO RECEIVE PATIENT PURCHASING DATA UPON REQUEST TO THE DEPARTMENT

Chapter 124E does not authorize the Department to provide patient purchasing information back to a certifying provider, as is the case with the traditional PDMP. The Board recommends that authority be given to the Department to provide patient purchasing information to providers for patients they have certified.

7. IMPROVEMENTS IN THE PATIENT PROVIDER RELATIONSHIP, AND OVERSIGHT OF TELEHEALTH CONSULTATIONS

The Board has expressed concern with telehealth providers who may not be maintaining patient-provider relationships with patients they are certifying, or do not establish care with patients in the traditional sense. The Board recommends the citation of the Board of Medicine's rules around standards of practice for telemedicine (**653 IAC 13.11(7)** in Chapter 124E.

8. SEEK A FEDERAL EXEMPTION FOR IOWA'S PROGRAM

The Board recommends that a task force of legal experts be authorized, similar to the current board of medical experts, to assist the department in navigating the legal issues involved with requesting an exemption for Iowa's program from necessary Federal agencies. This is related to a recommendation in the Board's 2019 Annual Report and the passage of **HF2589** in June, 2020.

IV. MANUFACTURER AND DISPENSARY LICENSING

MANUFACTURING

On September 8, 2020 the Department posted an RFP to license a second manufacturer. On December 22, 2020 the Department posted a Notice of Intent to Award this license to ICC MFG Holdings, LLC for Cedar Rapids, and issued this license on February 17, 2021. A formal request was made, and approved by the Department, to extend the operational timeline of the manufacturing facility to June 1, 2022. An additional request was made to relocate the location of the manufacturing facility from Cedar Rapids to Iowa City, and a new operational timeline of May 1, 2023 was approved by the Department.

DISPENSING

On December 15, 2020, the Department posted RFPs to license new dispensaries in Western and Eastern Iowa. On February 15, 2021 the Department posted Notices of Intent to Award these licences to Iowa Cannabis Company West, LLC in Council Bluffs, and Iowa Cannabis Company East, LLC in Iowa City, and issued these licenses on March 19, 2021. Both RFPs included an operational deadline of July 1, 2021. A formal request for extension of this timeline to December 1, 2021 was granted by the Department. Both dispensaries opened on or around October 1, 2021 to dispense Medical Cannabidiol Products to patients and caregivers. All five dispensaries were operational and dispensing to patients throughout calendar year 2022.

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2022 Program Data

The data for this report, unless otherwise noted, comes from the Department's Secure Sales and Inventory Tracking System and Patient Registry, a secure, web-based application system.

I. HEALTHCARE PRACTITIONERS

Healthcare practitioners are not required to complete specific training on medical cannabis prior to certifying a patient for the Iowa Medical Cannabidiol Program. A healthcare practitioner is defined as a physician (MD/DO), physician assistant (PA), advanced registered nurse practitioner (ARNP), or a podiatrist (DPM). Figure 1 depicts the number of healthcare practitioners (HCPs) in a month who have certified their first unique patient, as well as the cumulative number of HCPs who have certified at least one patient since the beginning of the program.

FIGURE 1.

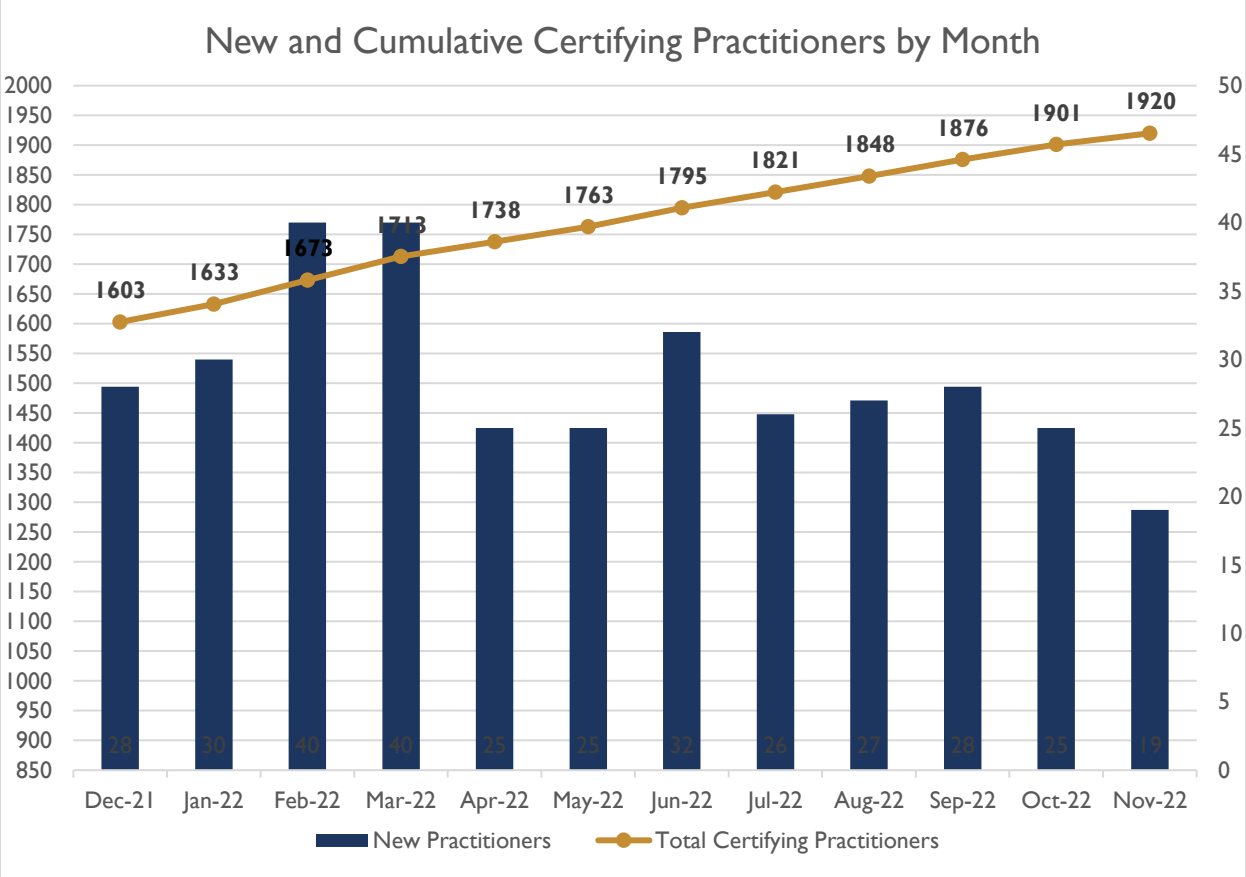
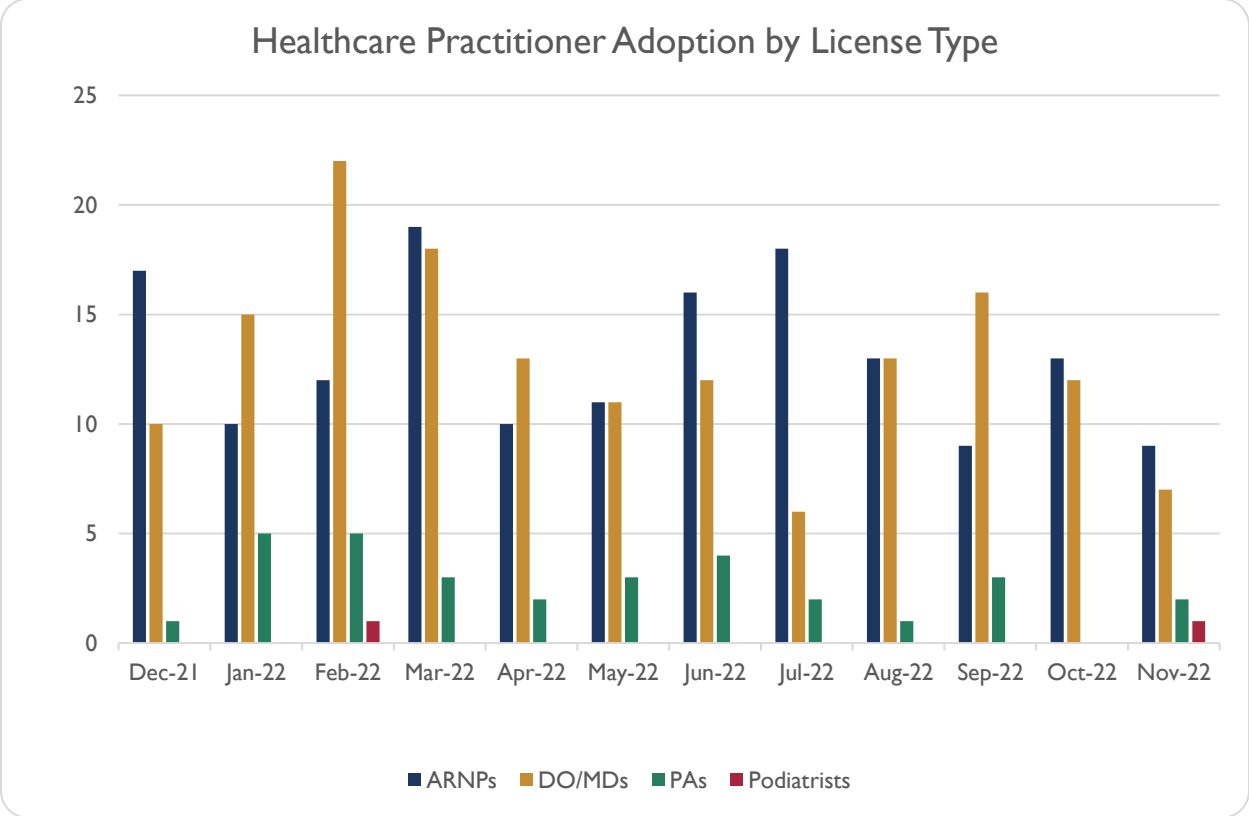


Figure 2 depicts the number of ARNPs, DO/MDs, PAs and podiatrists who have certified their first unique patient in the last year. Prior to July 1, 2020, ARNPs, PAs and podiatrists were not authorized to certify patients.

FIGURE 2

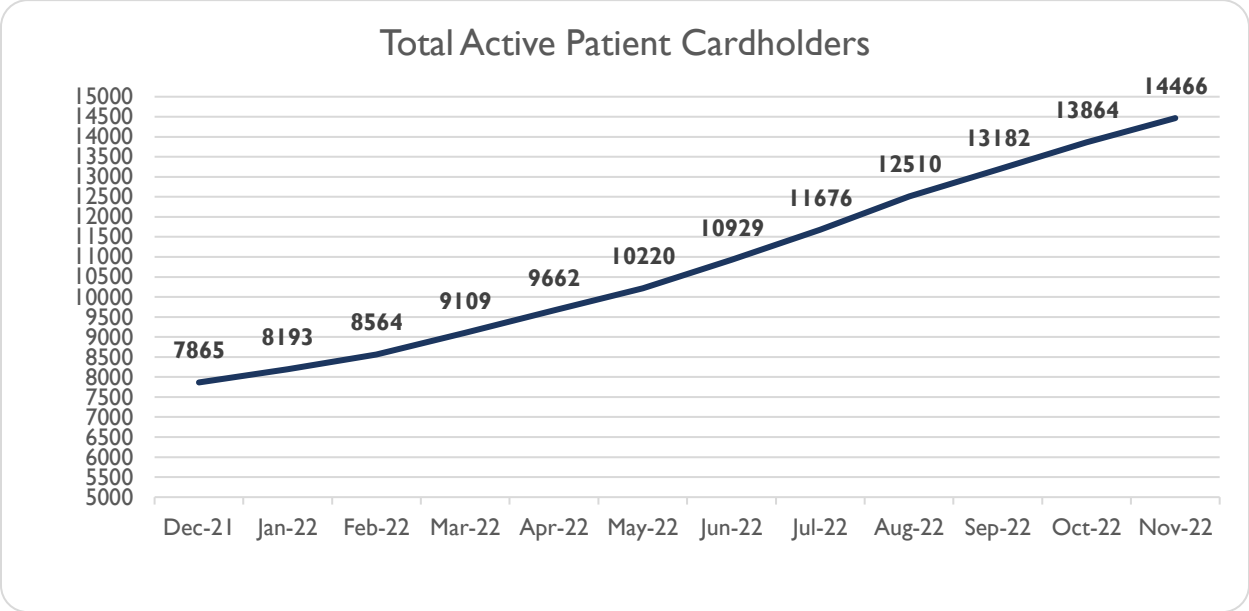


II. PATIENTS AND CAREGIVERS

In order to purchase medical cannabidiol products from Iowa's licensed dispensaries, patients must have their qualifying medical condition certified by a Healthcare Practitioner. Once certified, a patient can apply for a registration card that is valid for one year.

Figure 3 depicts the number of patients with active registration cards in each month of 2022. Prior to July 1, 2020 registration cards were issued by the Iowa Department of Transportation. IDPH began issuing cards on July 1, 2020.

FIGURE 3



Designated caregivers are individuals who are certified by a patient's healthcare practitioner to purchase and possess medical cannabidiol products on behalf of a patient. A caregiver is designated if a patient is too ill, immobilized or otherwise unable to visit a dispensary. Figure 4 depicts the number of caregiver registration cards issued in each month of 2022. The cumulative number of caregiver cards issued since the beginning of the program is also depicted as a trend line.

FIGURE 4

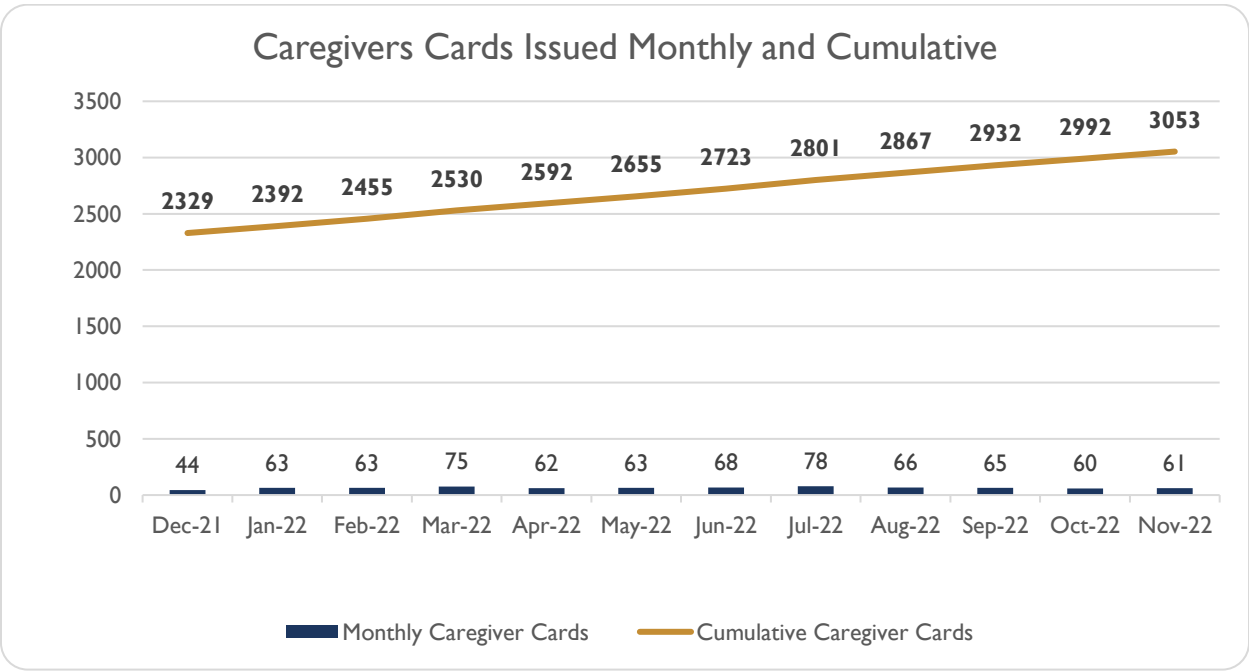


Figure 5 depicts the number of registration cards issued to patients in each month of 2022. The monthly patient cards issued includes new patients, as well as patients who may have renewed their registration card. The cumulative numbers of patient cards issued since the beginning of the program are displayed using a trend line.

FIGURE 5

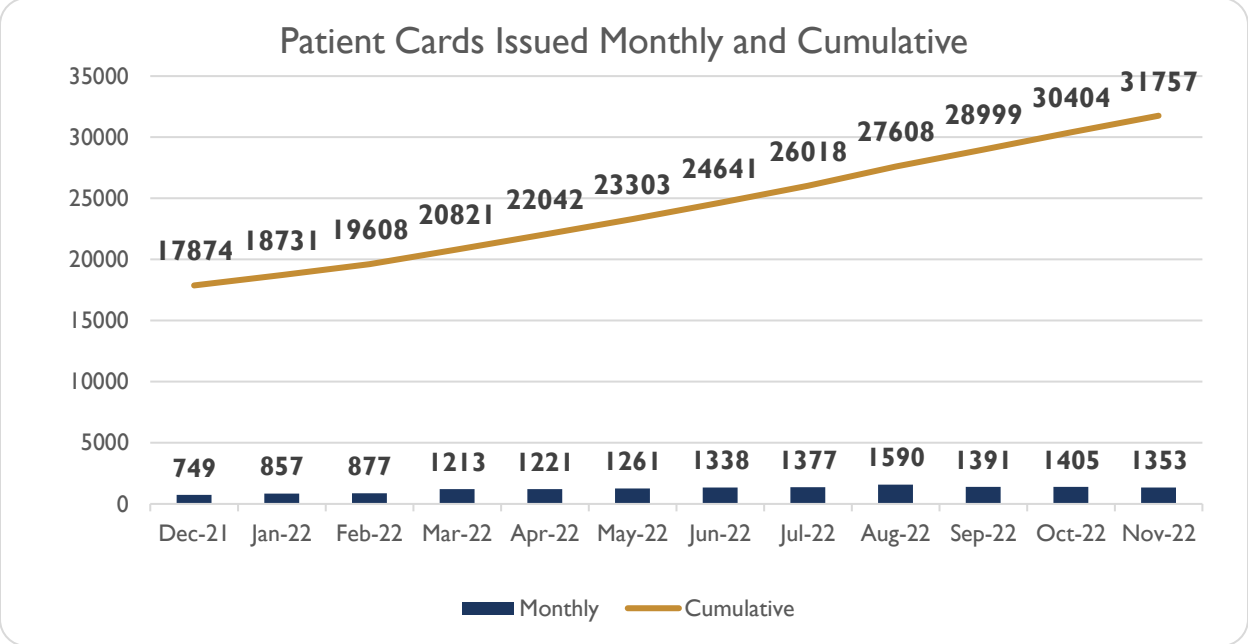


Figure 6 depicts the certifications by age bracket for each qualifying debilitating medical condition for all active patient cardholders.

FIGURE 6

Age	AIDS/ HIV	ALS	Autism	Cancer	Chronic Pain	Crohn's	MS	Parkinson's	PTSD	Seizures	Terminal Illness	Ulcerative Colitis	Total	% of Total
10 or Under			57		2	1			1	14			75	0.51%
11 - 17			45	3	12		1		9	11		1	82	0.56%
18 - 30	5	1	36	21	1044	22	11	3	706	44		10	1903	12.94%
31 - 40	11	1	12	46	2303	47	34	5	1036	80		25	3600	24.48%
41 - 50	7	2	1	93	2321	40	61	6	633	43	2	17	3226	21.94%
51 - 60	7	6	2	142	1952	23	42	22	293	21	3	8	2521	17.14%
61 - 70	11	5	3	229	1750	13	33	43	127	16	9	16	2255	15.33%
71 - 80	1			93	608	4	10	34	21	5	7	4	787	5.35%
81 - 90				25	179		2	15	3		1		225	1.53%
Over 90				4	27							1	32	0.22%
Grand Total	**42**	**15**	**156**	**656**	**10198**	**150**	**194**	**128**	**2829**	**234**	**22**	**82**	**14706**	**100.00%**

Figure 7 represents the patient population percentage by gender.

FIGURE 7

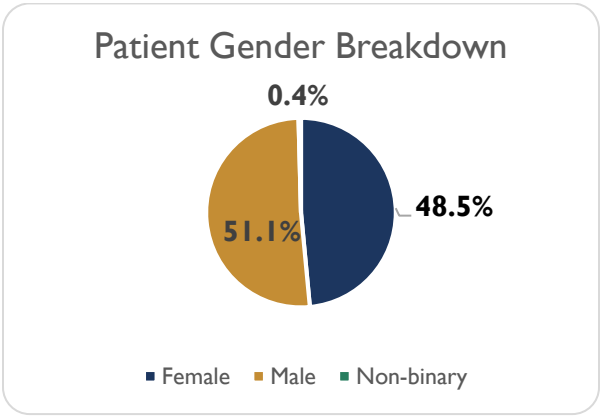
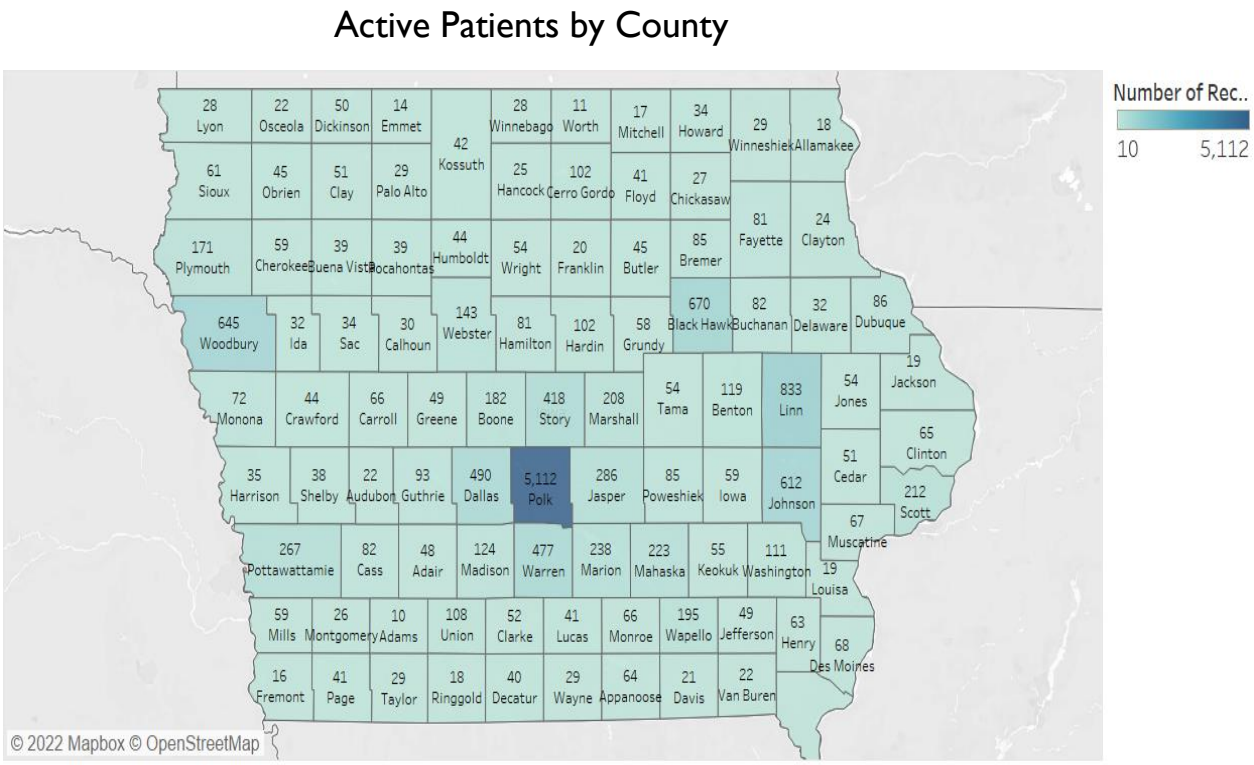


Figure 8 represents the density of active registration card-holders by county in Iowa.

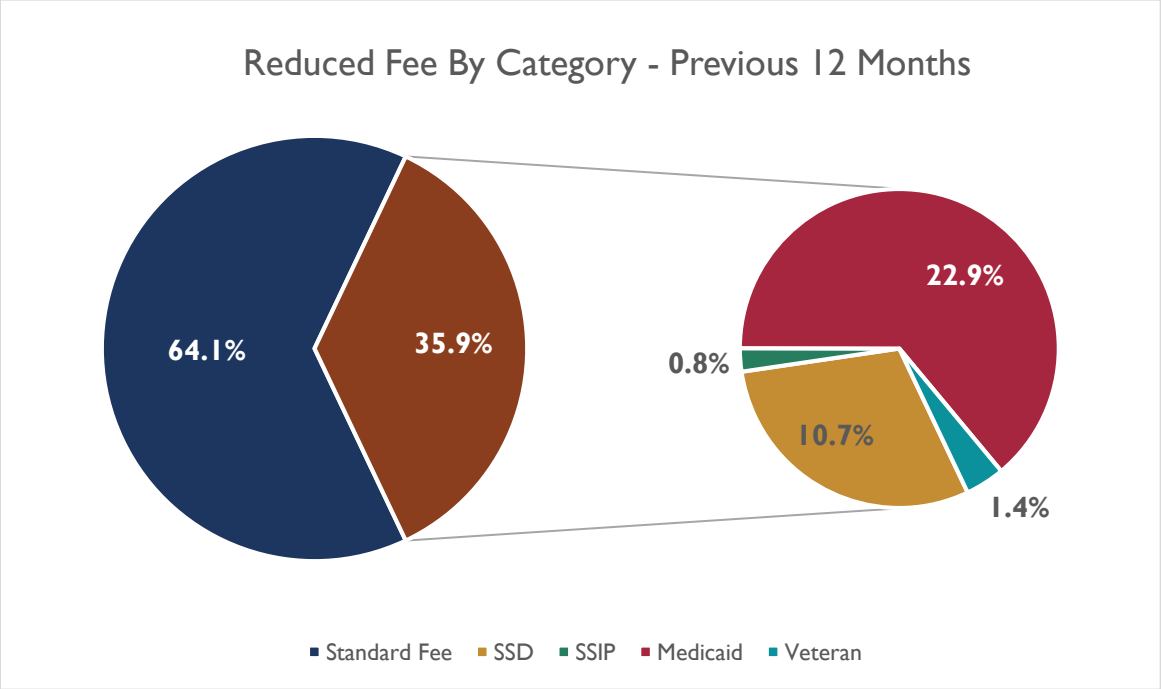
FIGURE 8.



Map based on Longitude (generated) and Latitude (generated). Color shows sum of Number of Records. The marks are labeled by sum of Number of Records and County. The data is filtered on Application Status, which keeps Approved and Issued.

Patients in Iowa are eligible for a reduced fee when applying for their medical cannabidiol registration card. If a patient can provide proof of Social Security Disability Insurance (SSDI), Supplemental Security Income (SSI), or Medicaid, they are eligible for a reduced fee. In 2022, via updates to administrative rule, proof of Veterans status became eligible for the reduced application fee. Figure 9 depicts the percentage of standard ($100) or reduced ($25) fee applications, as well as the percentage of each reduced fee type.

FIGURE 9



III. DISPENSARY SALES

Iowa's licensed dispensaries are required to transmit their medical cannabidiol dispensing data to the state's Secure Sales and Inventory Tracking System on a real-time basis.

Figure 10 depicts the number of unique patients who visited a dispensary in a given month in 2022, as well as the total dispensary visits each month during 2022.

FIGURE 10

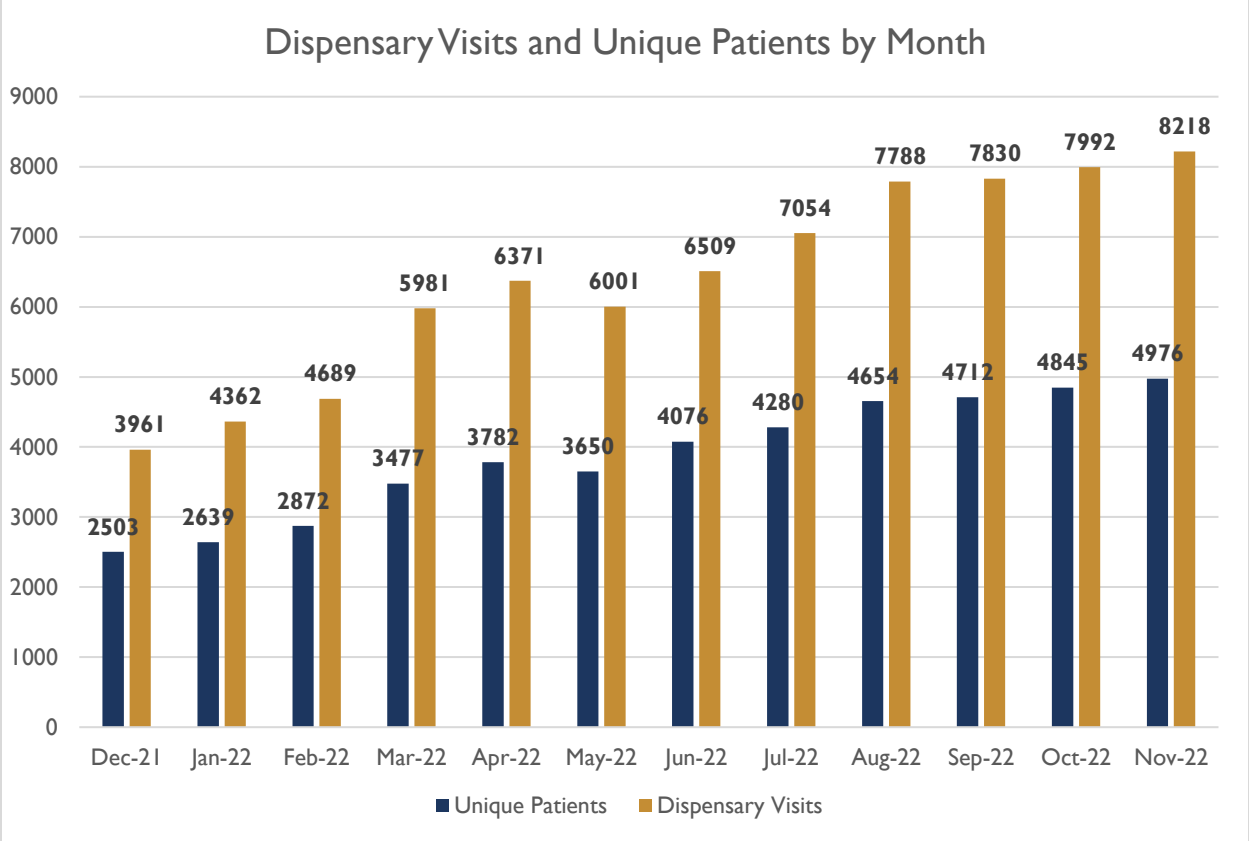


Figure 11 represents the average transaction price (excluding tax) amongst Iowa's licensed dispensaries during 2022.

FIGURE 11

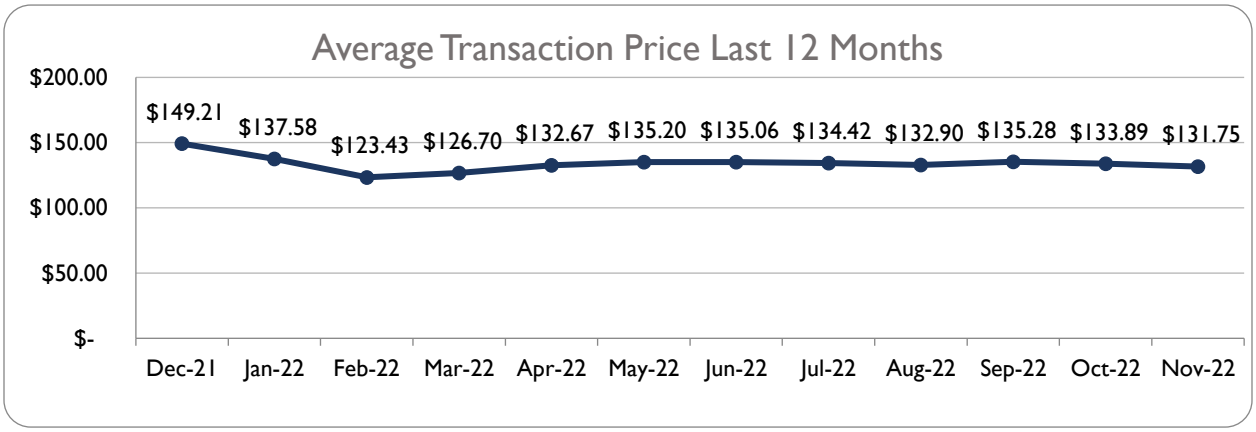
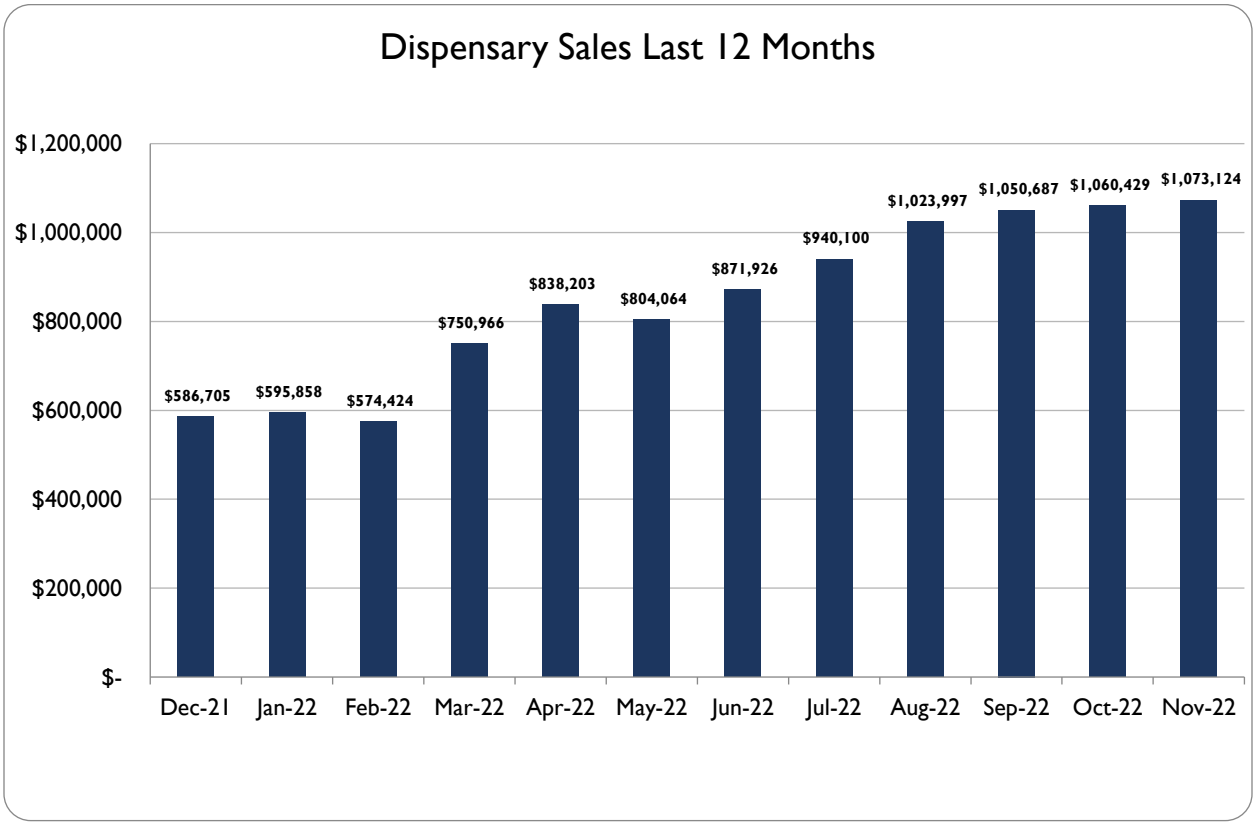


Figure 12 represents the total sales (excluding tax) in each month of 2022 among Iowa's licensed dispensaries. In calendar year 2022, the program saw **$10,170,483** in cumulative sales.

FIGURE 12



Chapter 124E allows Iowa's two licensed manufacturers 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, suppository forms and vaporized forms (vaporized forms became available for sale on August 7, 2019). Figures 13 & 14 depict the percentage of product sales in 2022 by formulation and product type.

FIGURE 13

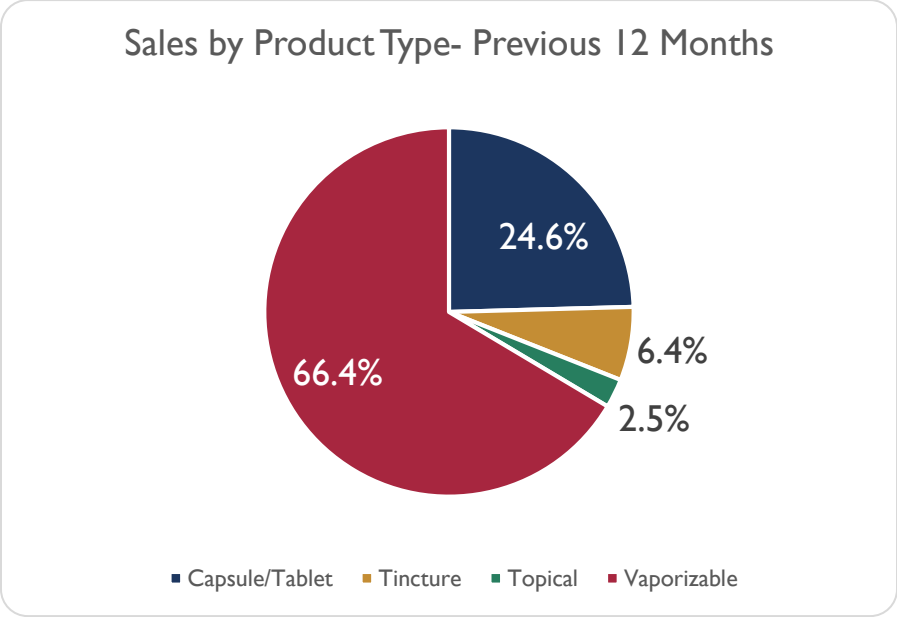


FIGURE 14

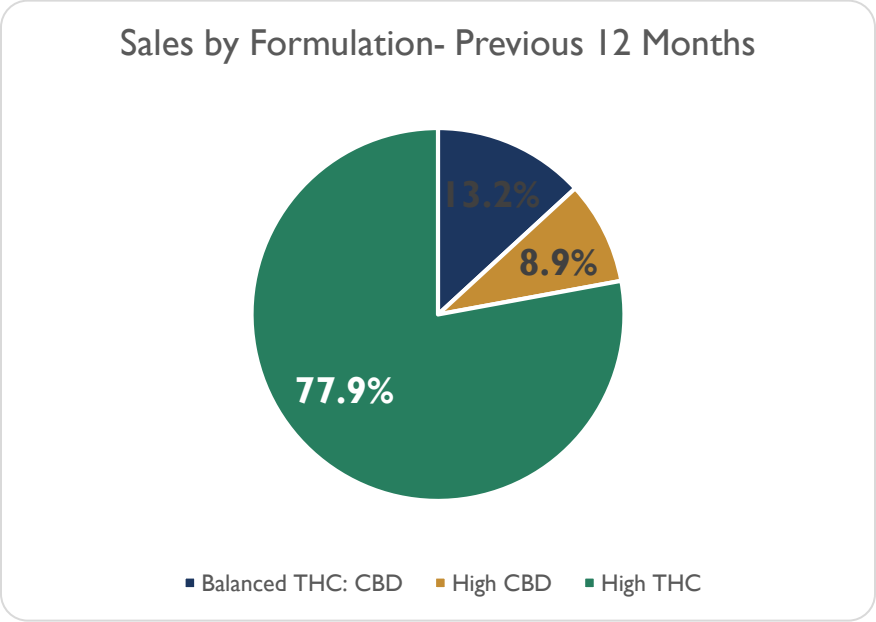
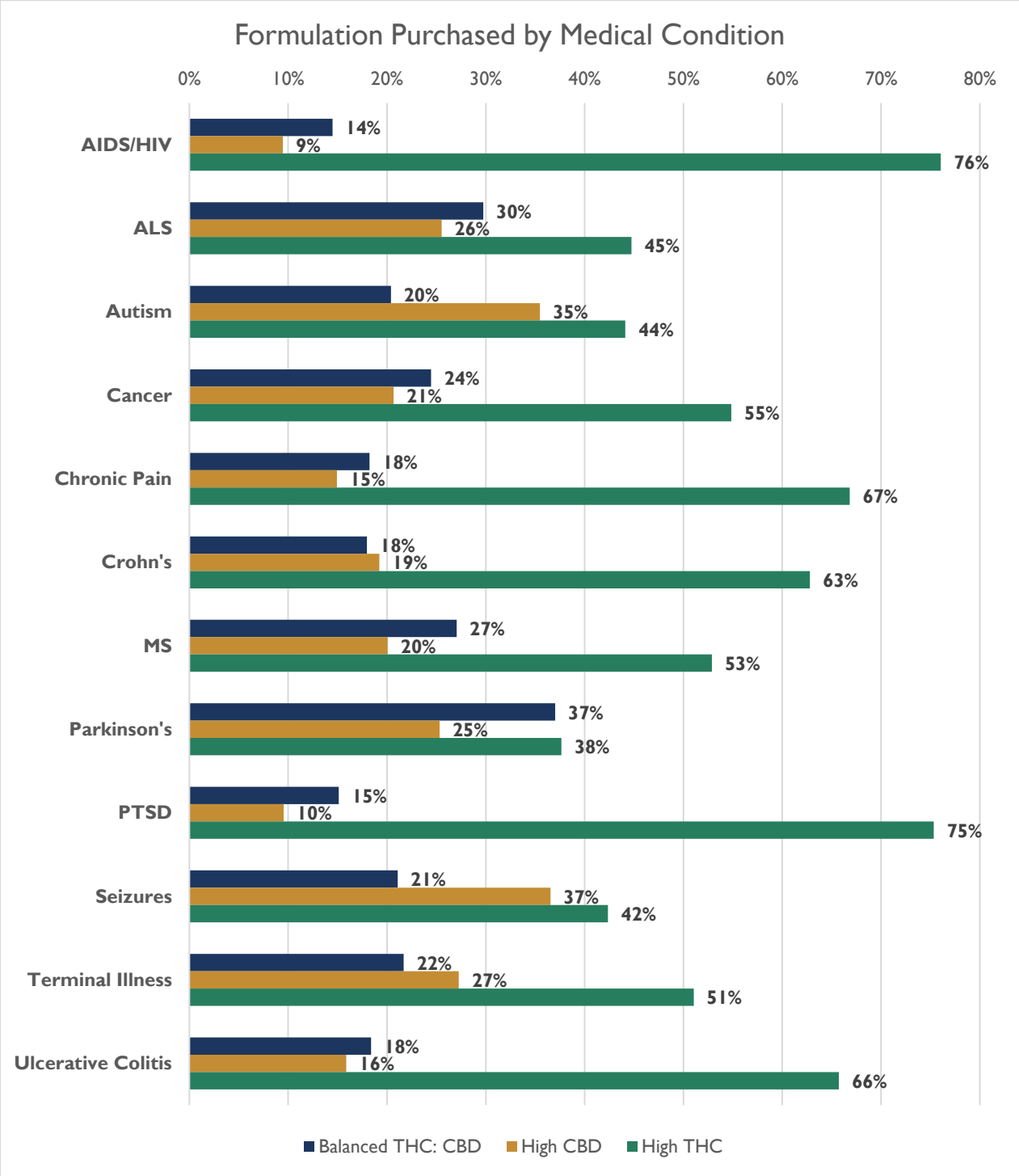


Figure 15 provides percentage-based purchasing behaviors for a given product formulation and qualifying condition.

FIGURE 15



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Product Testing and Adverse Event Reporting

Product safety and consistency is a primary 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, in 2022 or otherwise.

The protocol governing the testing of medical cannabidiol, as well as a testing process overview, can be found on the Office of Medical Cannabidiol's website.