2021 Annual Report

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

Authorship - Office of the Deputy Director, Bureau 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.

Table of Contents

List of Figures

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, recommendations for improvement, program highlights, and program data during calendar year 2021.

The mission of the Bureau of Medical Cannabidiol (BMC) at the Iowa Department of Public Health 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 debilitating medical condition, with the requirements to ensure the safety and efficacy of the products.

The BMC continues to oversee registration of patients and caregivers, as well as the manufacture, testing, and sale of medical cannabidiol products to ensure they are dispensed in a manner that protects public health and safety. The BMC places focus on IT automation and quality improvement in response to increases in volume, in order to meet program needs without added expenditures and staffing.

The data within the following figures and tables for this report were obtained through December 29, 2021, from the BMC 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 and Program

Board Meetings

The Board held four meetings during 2021.

1. February 19, 2021
2. May 21, 2021
3. August 20,2021
4. November 19, 2021

February 19, 2021

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 2020. He also notified the Board that accredited CMEs had been completed and were available to Iowa's certifying practitioners on the program's website. The Board also received notification that licenses had been issued for two new dispensaries in Council Bluffs and Iowa City, as well as a second manufacturing facility in Cedar Rapids.

May 21, 2021

At its May meeting, the Board did not consider any petitions for new qualifying conditions. Owen Parker, Bureau Chief, provided the Board a review of data from the first five months of 2021. Owen made the Board aware that Drs. Liesveld (psychiatry) and Cheyne (pediatrics) were not seeking to renew their Board seats, and that this left the Board with four vacancies beginning with the August, 2021 meeting. The Board requested a comparative analysis of the price of medical cannabis products in Iowa relative to similar medical programs. The Board was also notified that requests for funding guarantees pursuant to HF2589 had been sent to four Federal agencies (FDA, DEA, DOE, CMS).

August 20, 2021

At its August meeting, the Board did not consider any petitions for new qualifying conditions. Owen Parker, Bureau Chief, provided the Board a review of data from the first eight months of 2021. The Board received an update that the Council Bluffs and Iowa City dispensaries were expected to be open on or around October 1, 2021, and that the Department had approved a relocation of a second manufacturer from Cedar Rapids to Iowa City. The Board was notified that the program would be submitting updated rules as a part of the Departments FY22 regulatory plan. The Board preliminarily discussed its recommendations to the legislature for the 2021 annual report.

November 19, 2021

At its February meeting, the Board did not consider any petitions for new qualifying conditions. The Board received updates from Owen Parker, Bureau Chief, on data, new dispensary openings, and filling current Board vacancies. The Board finalized its 2021 recommendations to the legislature included herein.

Making Recommendations for Adding or Removing Medical Conditions[3]

In the calendar year 2021, there were no petitions for new qualifying debilitating medical conditions submitted by the public for the Board's consideration.

II. 2020 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*" was relevant prior to HF2589 and Iowa using a 3% THC limit on products. As Iowa now allows product formulations similar or the same to those allowed in other medical cannabis programs, it is congruent with the rest of the country to update the name. Since the passage of HF2589, the maintenance of the term "medical cannabidiol" has progressively created a knowledge and communication barrier, and 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 also been exacerbated by the recently implemented "consumable hemp" program, which provides OTC hemp-derived CBD and 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 recommendation is in lieu of a recommendation from the Board's 2020 Annual Report, which recommended a "satellite delivery" option. The Department consulted similar rural states who had considered a "satellite delivery" option, but opted not to implement it due to licensee feedback on economic viability, as well as compliance and security concerns voiced by local law enforcement.

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.

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

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. Veteran Eligibility for the Reduced Application Fee Option

The Board recommends that Chapter 124E.4 be amended to allow for Veterans to be eligible to receive the reduced application fee option pursuant to the submission of necessary documentation.

III. Licensure of Medical Cannabidiol Dispensaries

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 licenses 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.

IV. Licensure of Medical Cannabidiol Manufacturer

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, which was approved pursuant to receiving local zoning authority from the local municipality.

V. Providing Medical Cannabis CMEs for Iowa's Healthcare Practitioners

In April, 2019, in collaboration with the University of Iowa College of Public Health, the BMC released a survey through the Board of Medicine's list served to determine healthcare practitioner understanding of Iowa's program and to receive feedback for improvement. In response to practitioner feedback that a barrier to patient certification was a lack of knowledge about medical cannabis, the BMC worked with multiple services to provide accredited CMEs for practitioners. In February, 2021, medical cannabis CMEs that included education about the specific mechanics of Iowa's program were made available by The Answer Page and The Medical Cannabis Institute. The program also began hosting guidance documents for condition-specific treatment with medical cannabis, which were developed by the Center for Medical Cannabis at the Utah Department of Public Health.

VI. 2021 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. A final update to the data included herein was made on December 29, 2021.

1. 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.

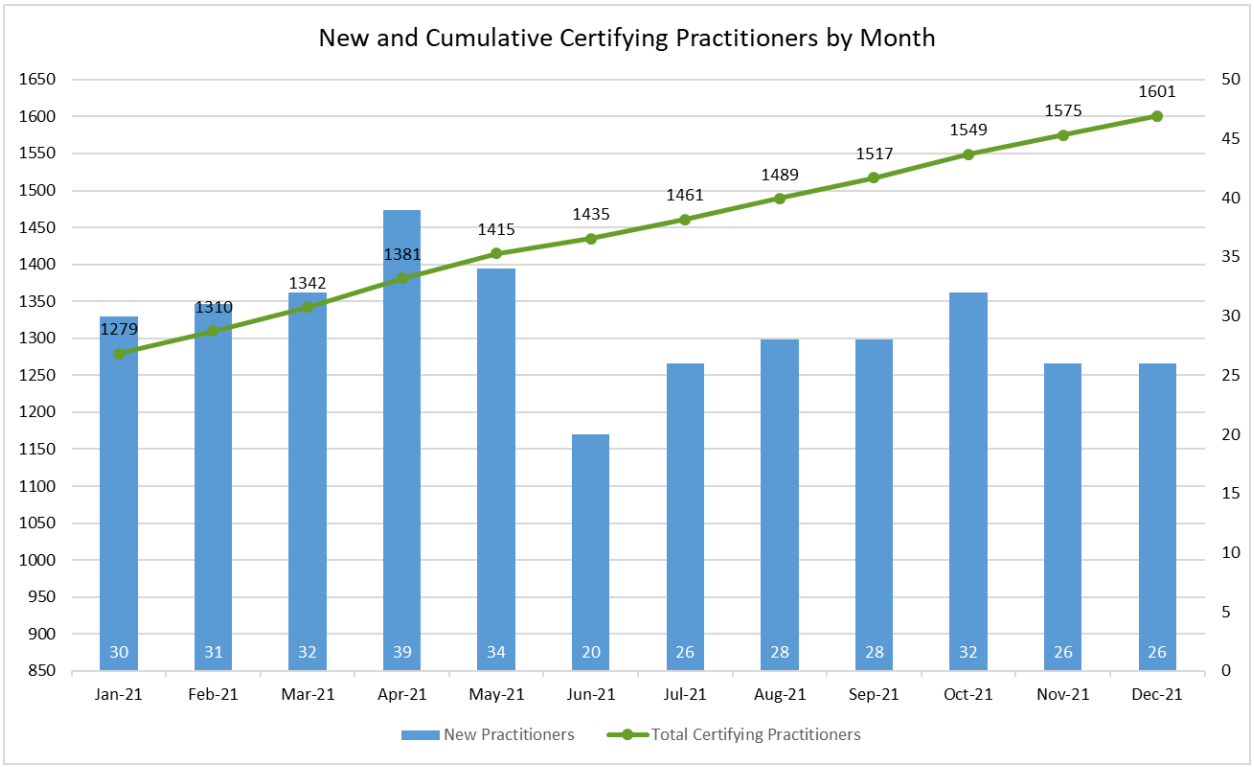
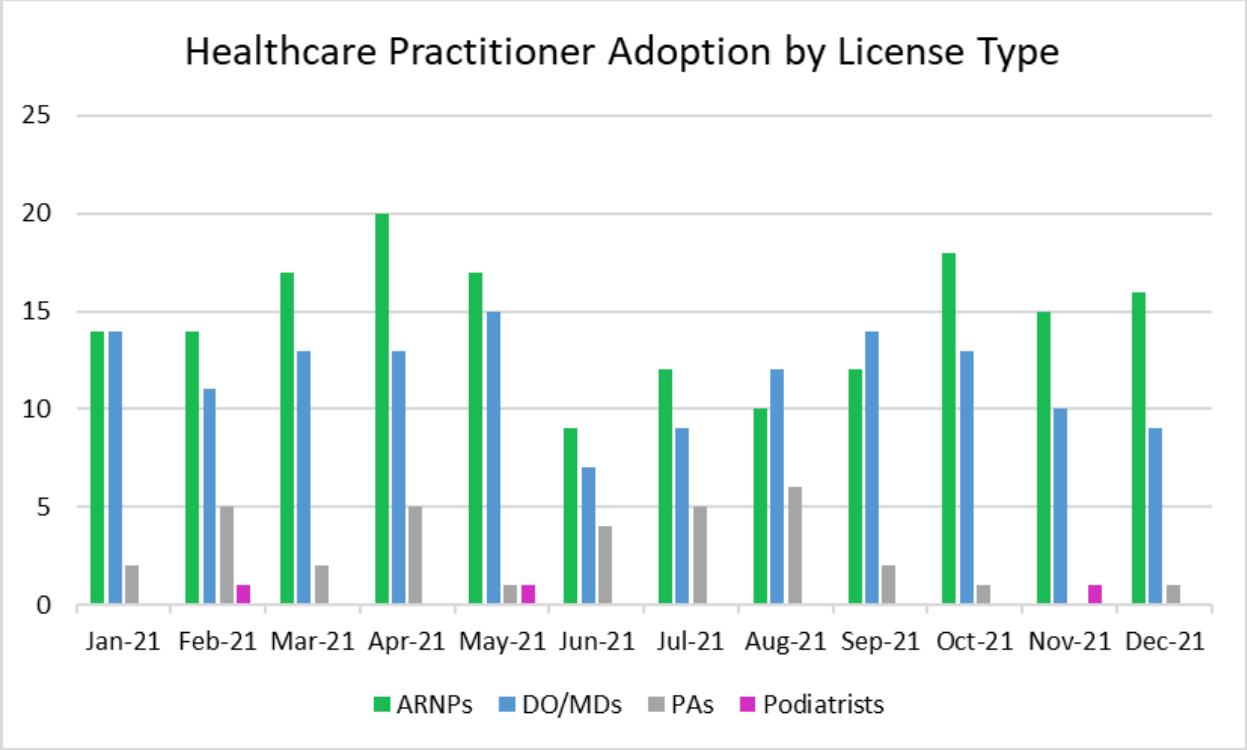


Figure 2 depicts the number of ARNPs, DO/MDs, PAs and podiatrists who have certified their first unique patient. Prior to July 1, 2020, ARNPs, PAs and podiatrists could not certify patients.

Figure 2.



2. 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 2020. 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.

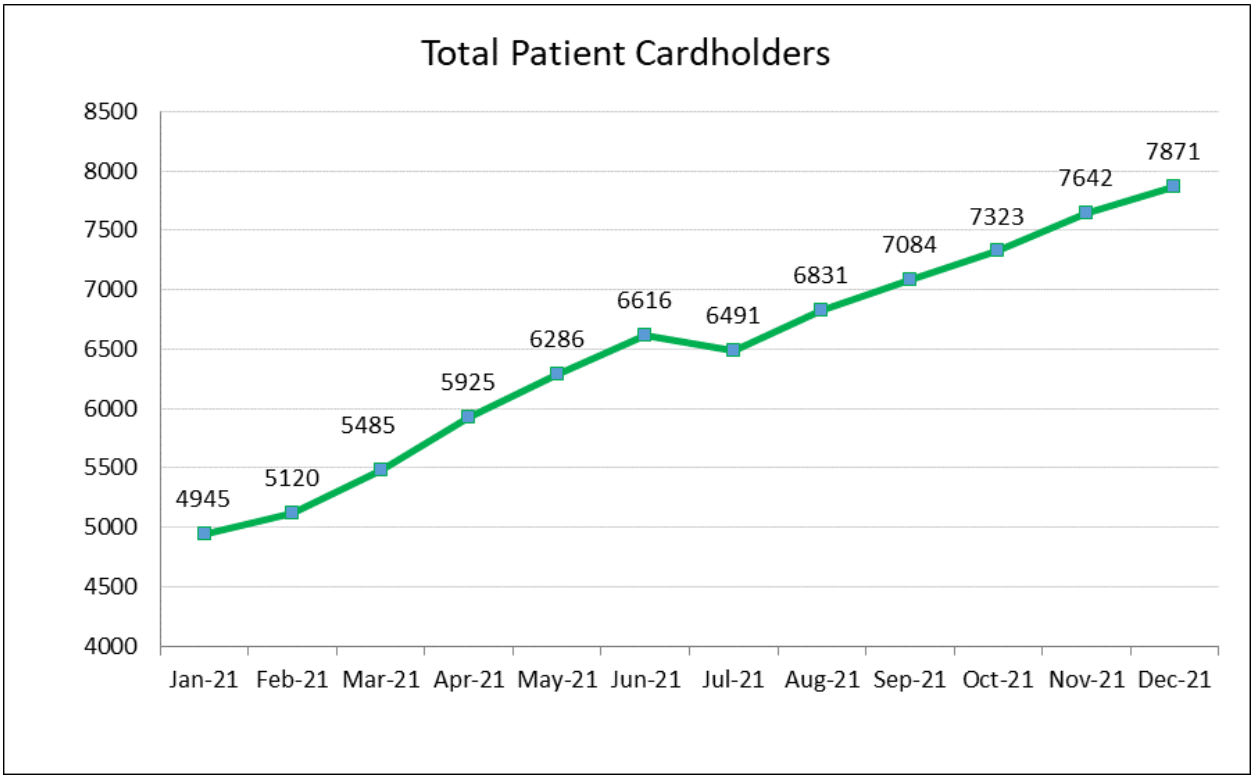


Figure 4 depicts the number of registration cards issued to patients in each month of 2020. The monthly patient cards issued includes new patients, as well as patients who may have renewed their registration card. The cumulative numbers of patient cards issued since the beginning of the program are displayed using a trend line.

Figure 4.

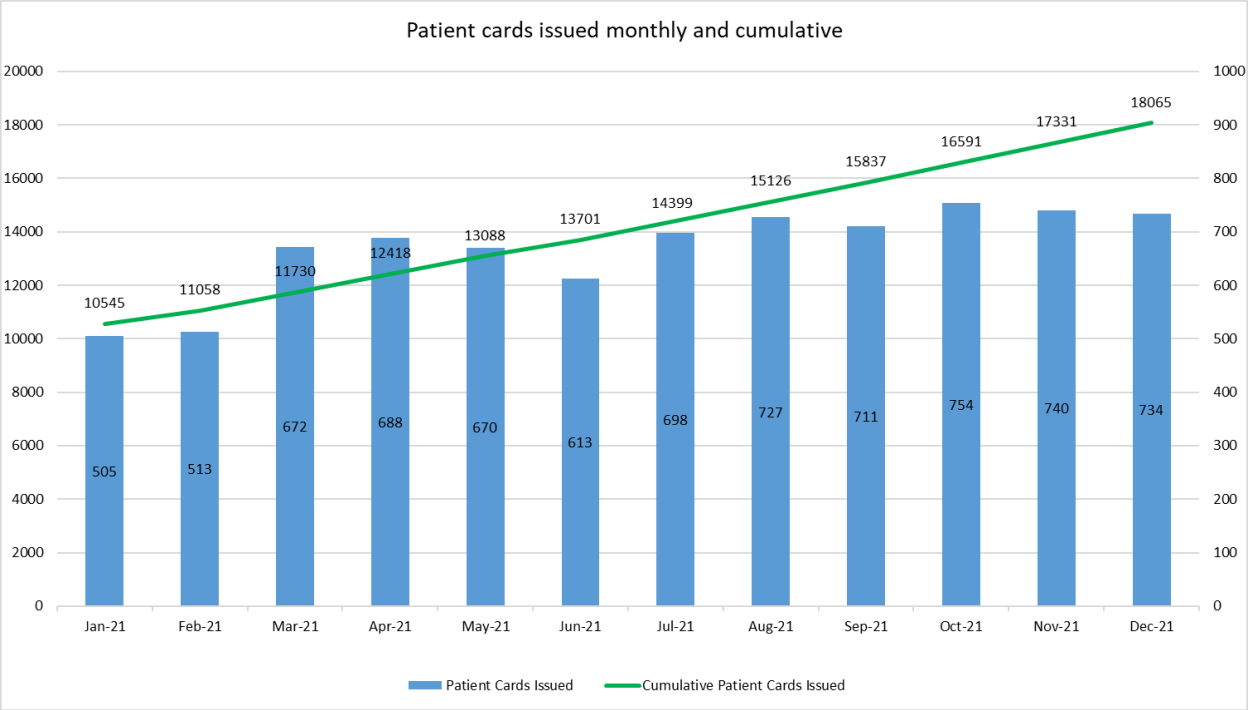


Figure 5 depicts the certifications by age group for each qualifying debilitating medical condition for all active patient cardholders.

Figure 5.

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	*	*	49	*	*	*	*	*	*	17	*	*	71	0.90%
11 - 17	*	*	34	*	12	*	*	*	8	12	*	*	70	0.89%
18 - 30	*	*	33	15	416	19	*	*	269	47	*	8	817	10.39%
31 - 40	*	*	*	46	1018	35	32	*	403	41	*	15	1605	20.40%
41 - 50	8	*	*	71	1094	24	54	7	243	32	*	14	1552	19.73%
51 - 60	10	*	*	95	1225	18	53	19	124	21	*	7	1579	20.07%
61 - 70	*	*	*	143	1077	13	36	34	50	6	*	*	1374	17.47%
71 - 80	*	*	*	56	470	*	12	33	21	*	*	*	606	7.70%
81 - 90	*	*	*	18	129	*	*	18	*	*	*	*	171	2.17%
Over 90	*	*	*	*	18	*	*	*	*	*	*	*	22	0.28%
Total	**30**	**10**	**124**	**448**	**5463**	**113**	**192**	**119**	**1118**	**182**	**18**	**50**	**7867**	
% of Total	**0.38%**	**0.13%**	**1.58%**	**5.69%**	**69.44%**	**1.44%**	**2.44%**	**1.51%**	**14.21%**	**2.31%**	**0.23%**	**0.64%**		

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.

Figure 6 represents the patient population percentage by gender.

Figure 6.

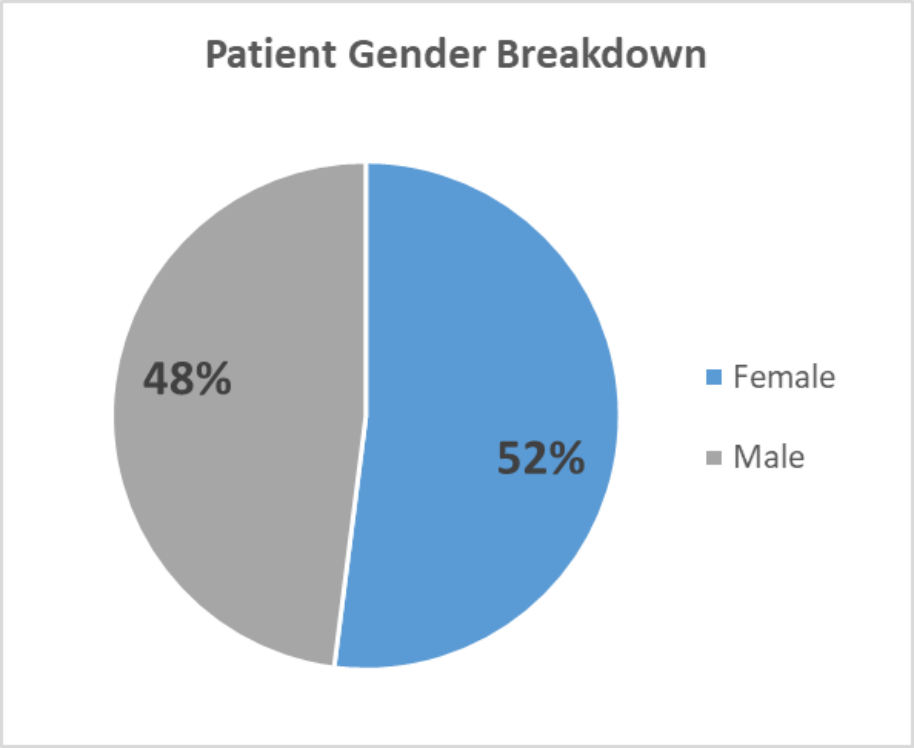
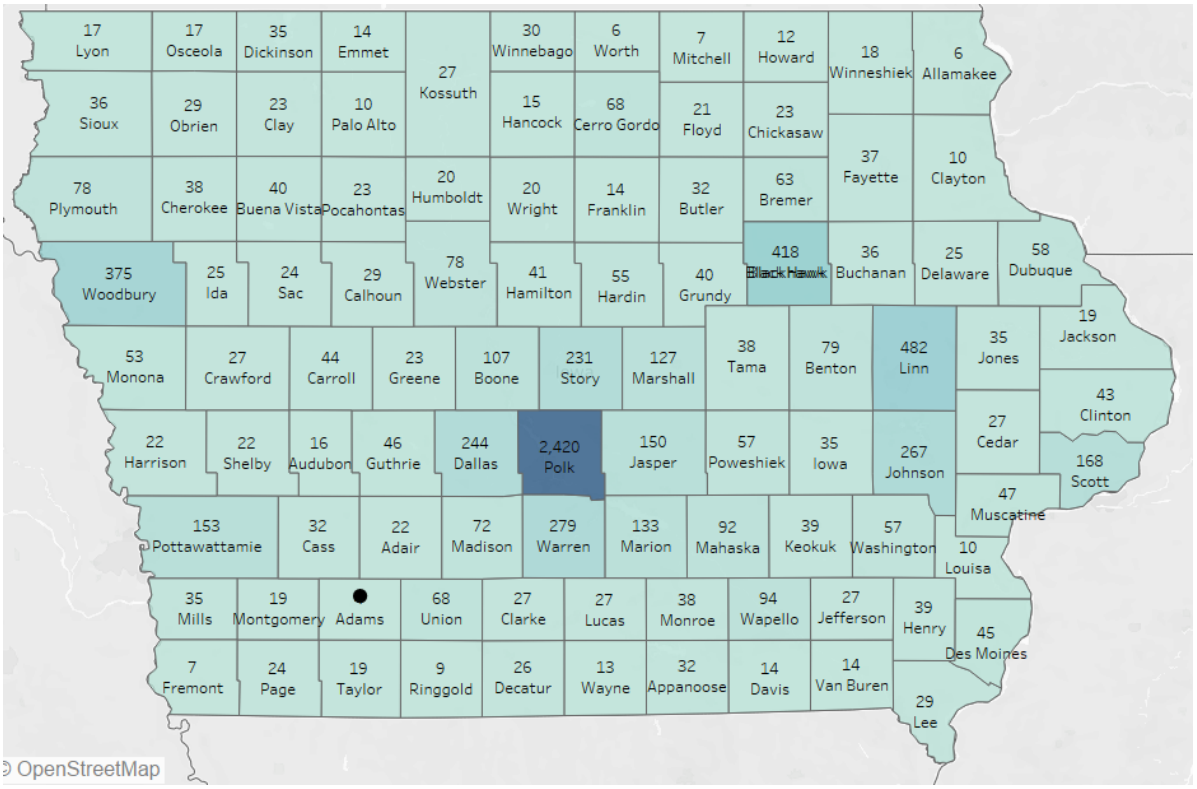


Figure 7 represents the density of active registration cardholders by county in Iowa.

Figure 7.

Medical Cannabidiol Registration Cardholders by County

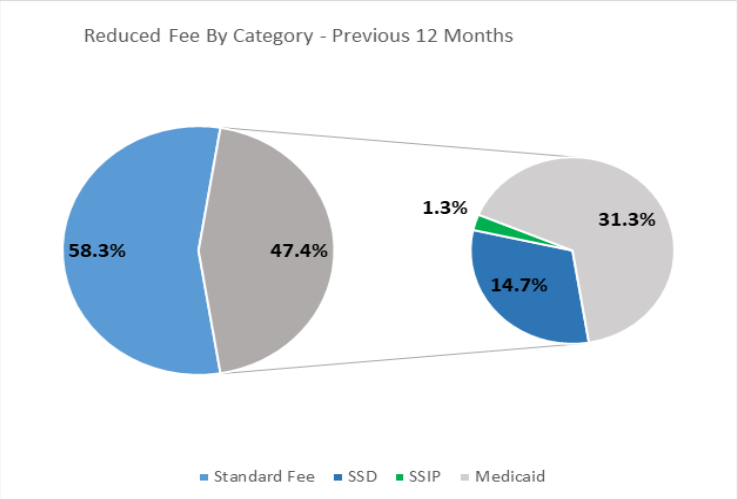


*Note: Values of < 5 are indicated by **

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.

Figure 8 depicts the percentage of standard ($100) or reduced ($25) fee applications, as well as the percentage of each reduced fee type.

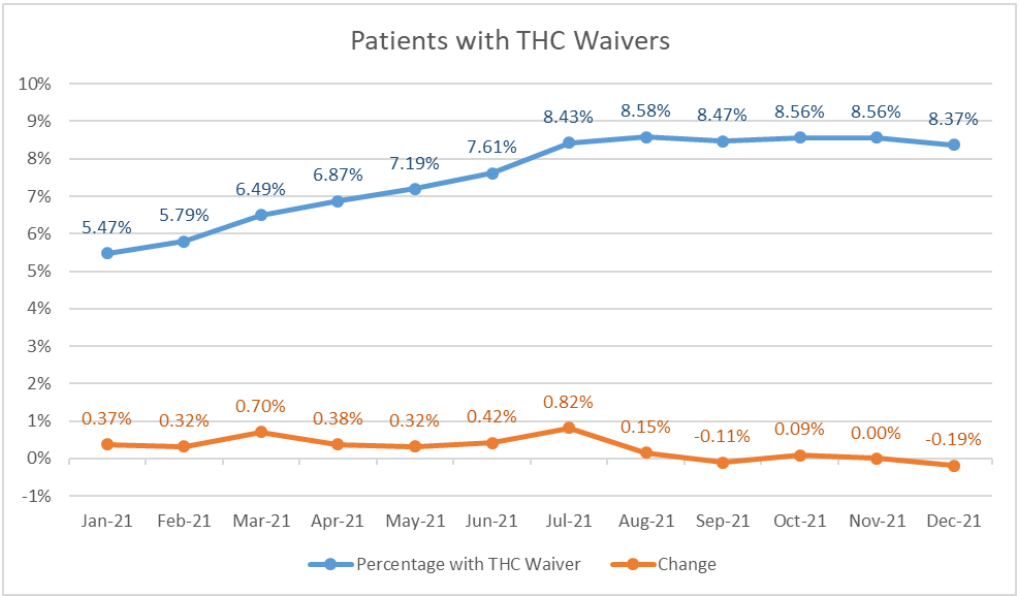
Figure 8.



Patients in Iowa are eligible to receive a waiver to the 4.5g THC per 90-day purchase limit after having participated in the program. Eligible Iowans include, patients with terminal illnesses, those whose original certifying practitioner certifies them to be able to purchase additional THC per 90 days.

Figure 9 depicts the percentage of the patient population possessing a waiver, and the percent change in that percentage month-over-month.

Figure 9.



A patient's medical cannabidiol registration card is valid for one year from the date of issuance.

Figure 10 represents the number of cards expiring each month as compared to the number of renewal applications and the monthly renewal rate. **Figure 11** represents patient renewals at different time-periods within card expiration.

Figure 10.

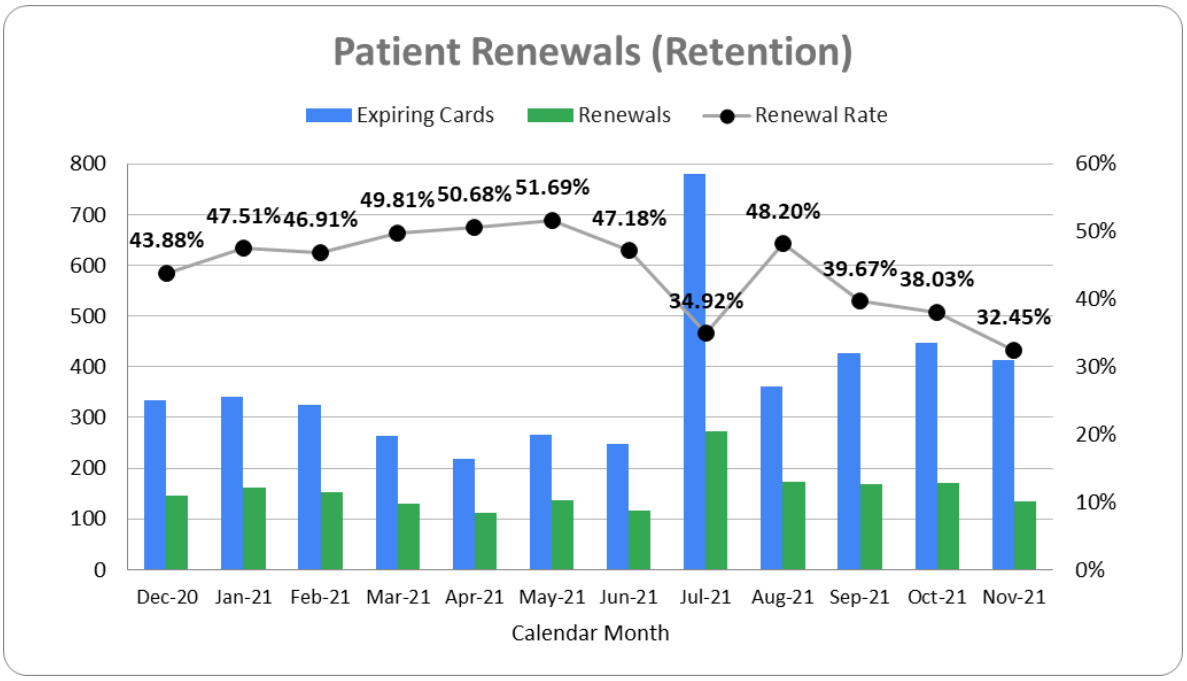
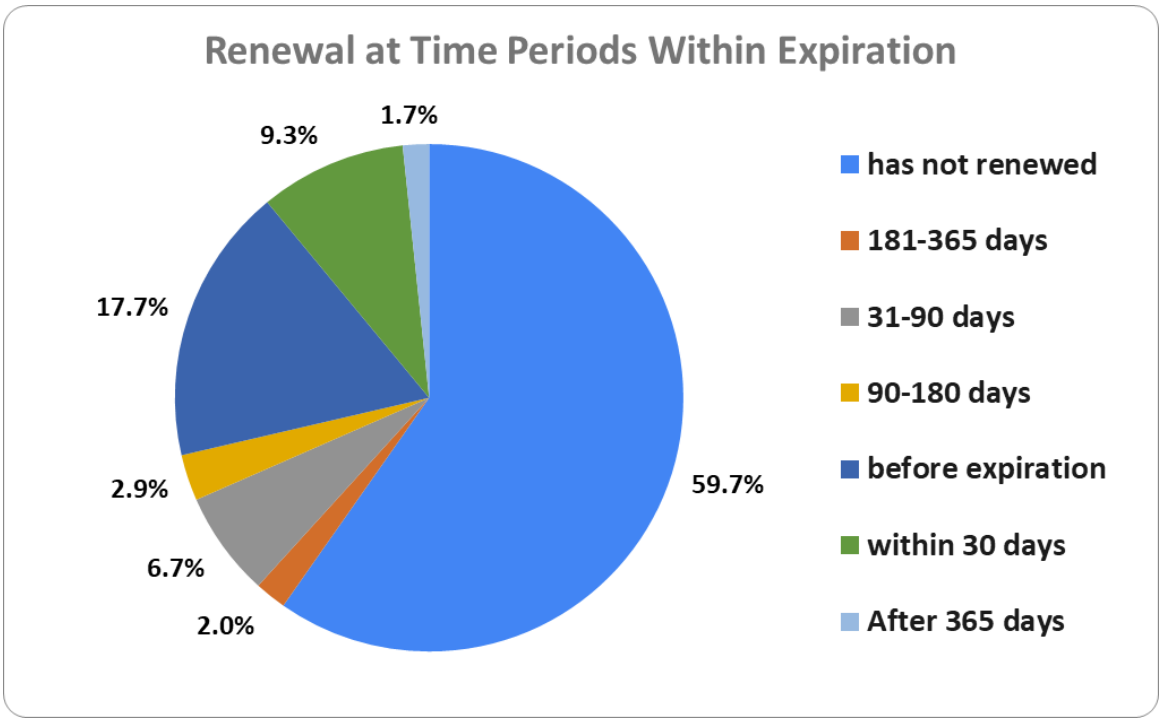
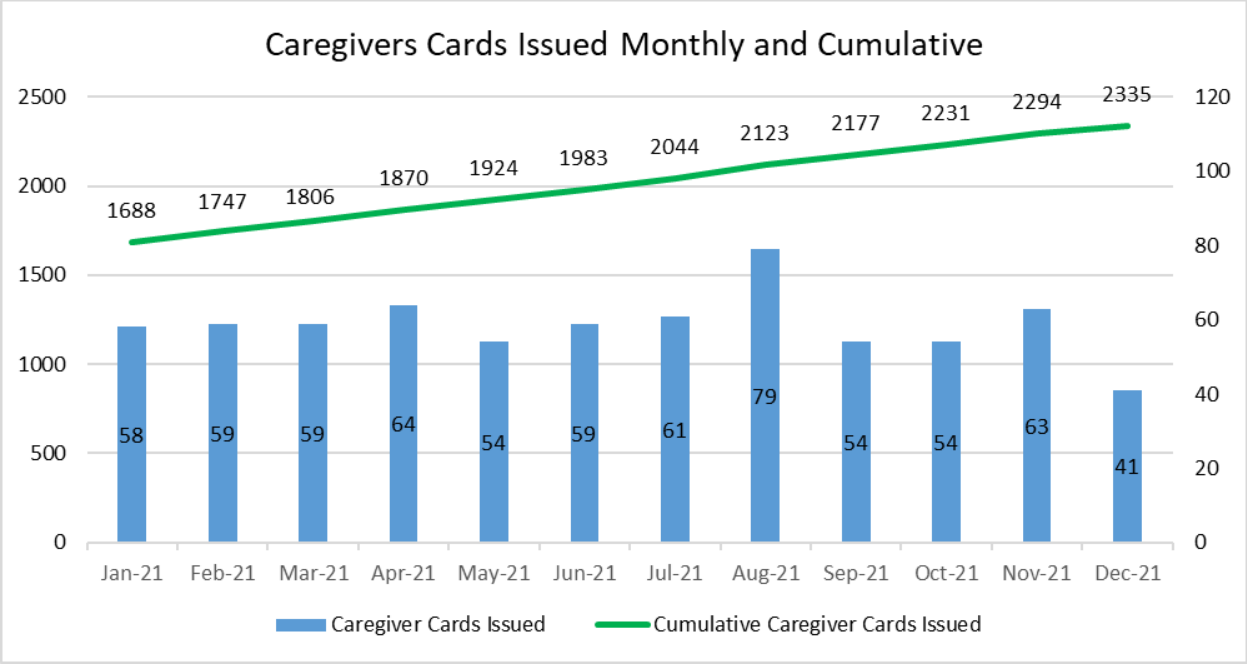


Figure 11.



Designated caregivers are individuals 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 12** depicts the number of caregiver registration cards issued in each month of 2020. The cumulative number of caregiver cards issued since the beginning of the program is also depicted as a trend line.

Figure 12.



3. 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 12 depicts the number of unique patients who visited a dispensary in a given month in 2020, as well as the total dispensary visits each month during 2020.

Figure 13 depicts the number of unique patients who visited a dispensary in a given month in 2020, as well as the total dispensary visits each month during 2020.

Figure 13.

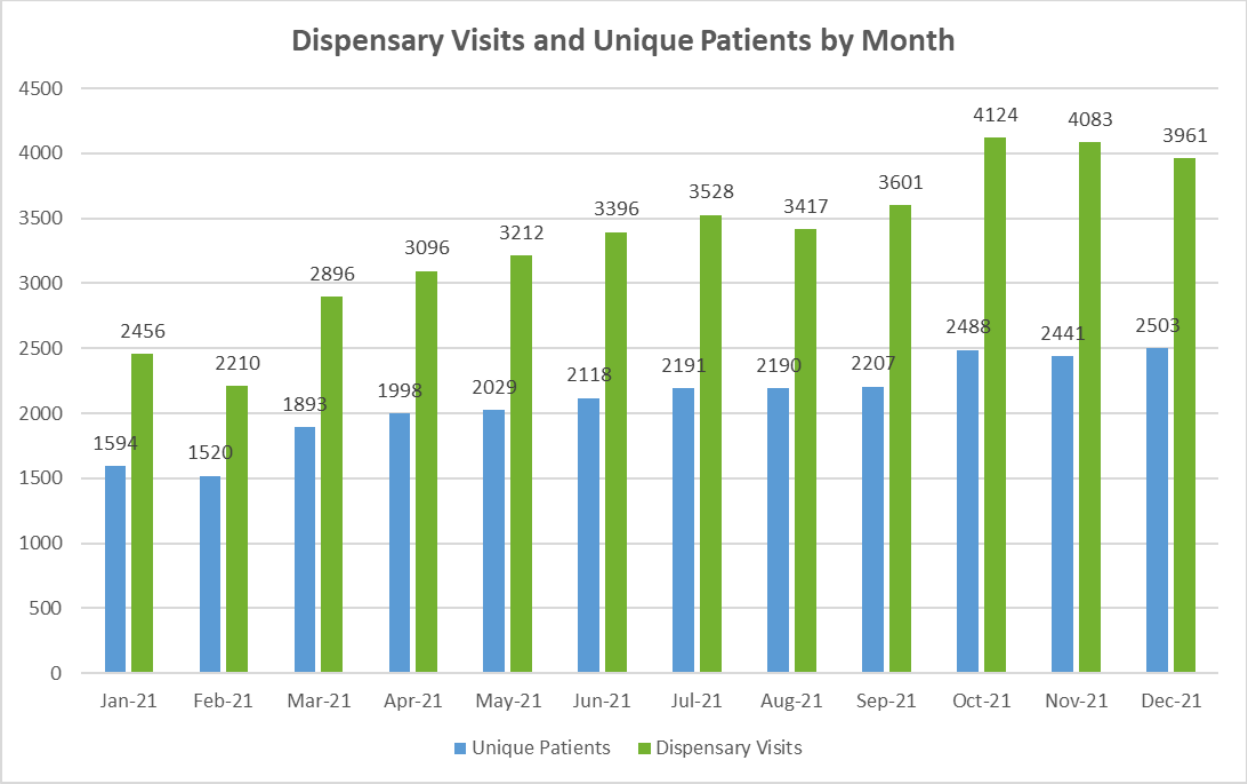


Figure 14 represents the average transaction price (excluding tax) amongst Iowa's licensed dispensaries during 2020.

Figure 14.

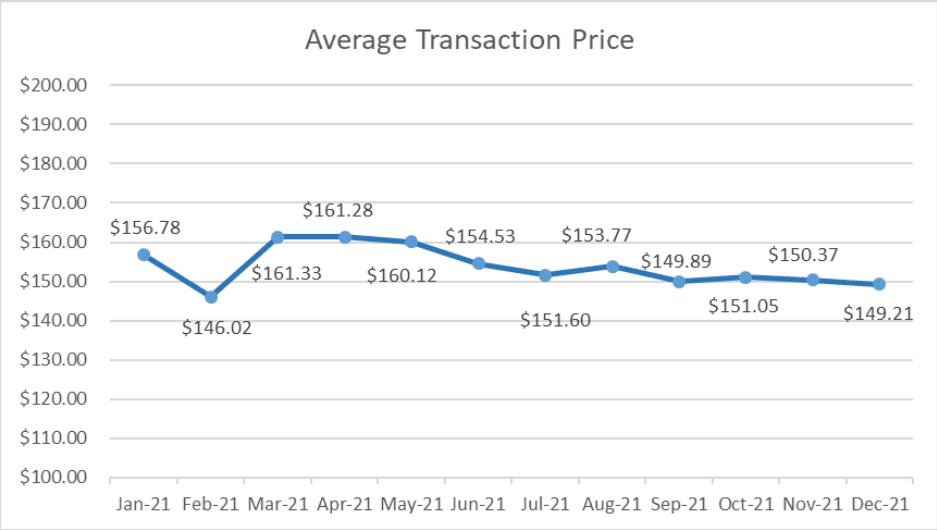
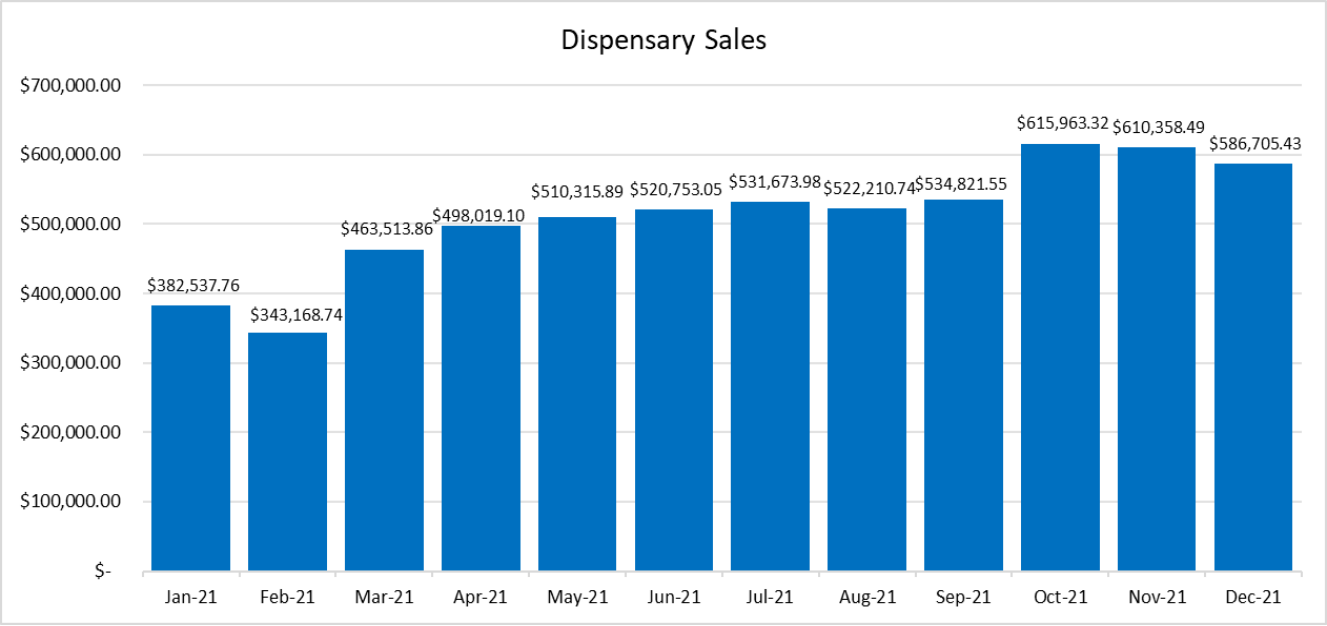


Figure 15 represents the total sales (excluding tax) in each month of 2020 among Iowa's licensed dispensaries. In calendar year 2020, the program saw $3,518,415.81 in cumulative sales.

Figure 15.



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 16 & 17** depict the percentage of product sales in 2020 by formulation and product type.

Figure 16.

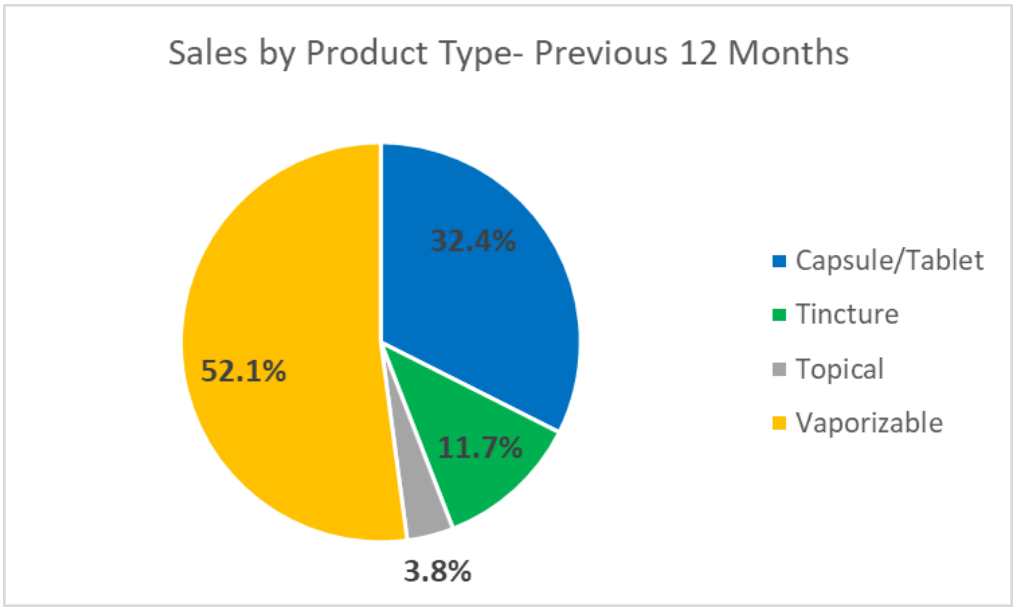


Figure 17.

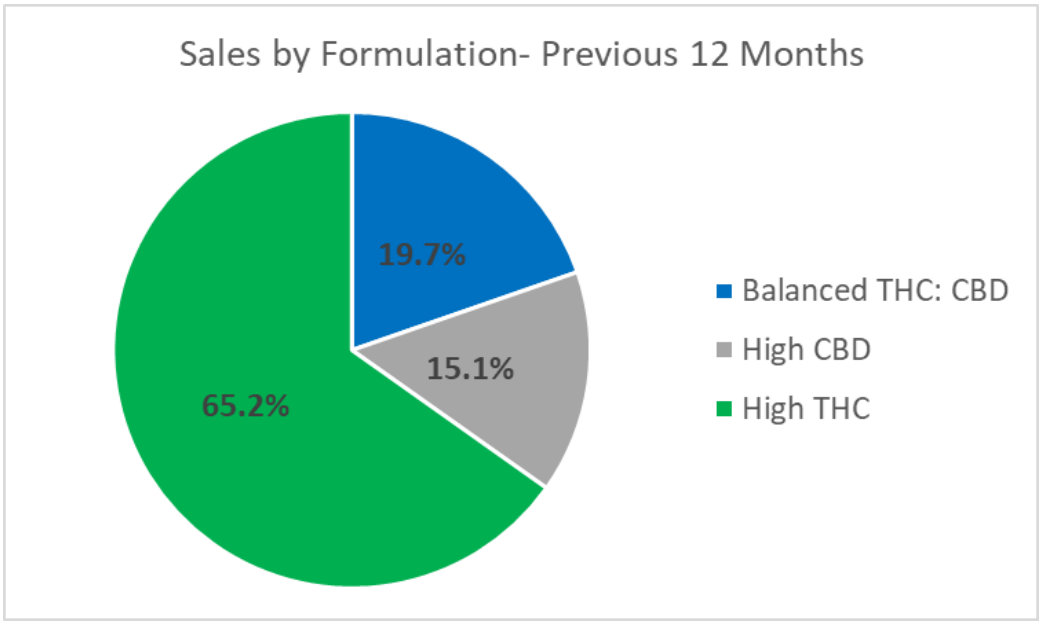
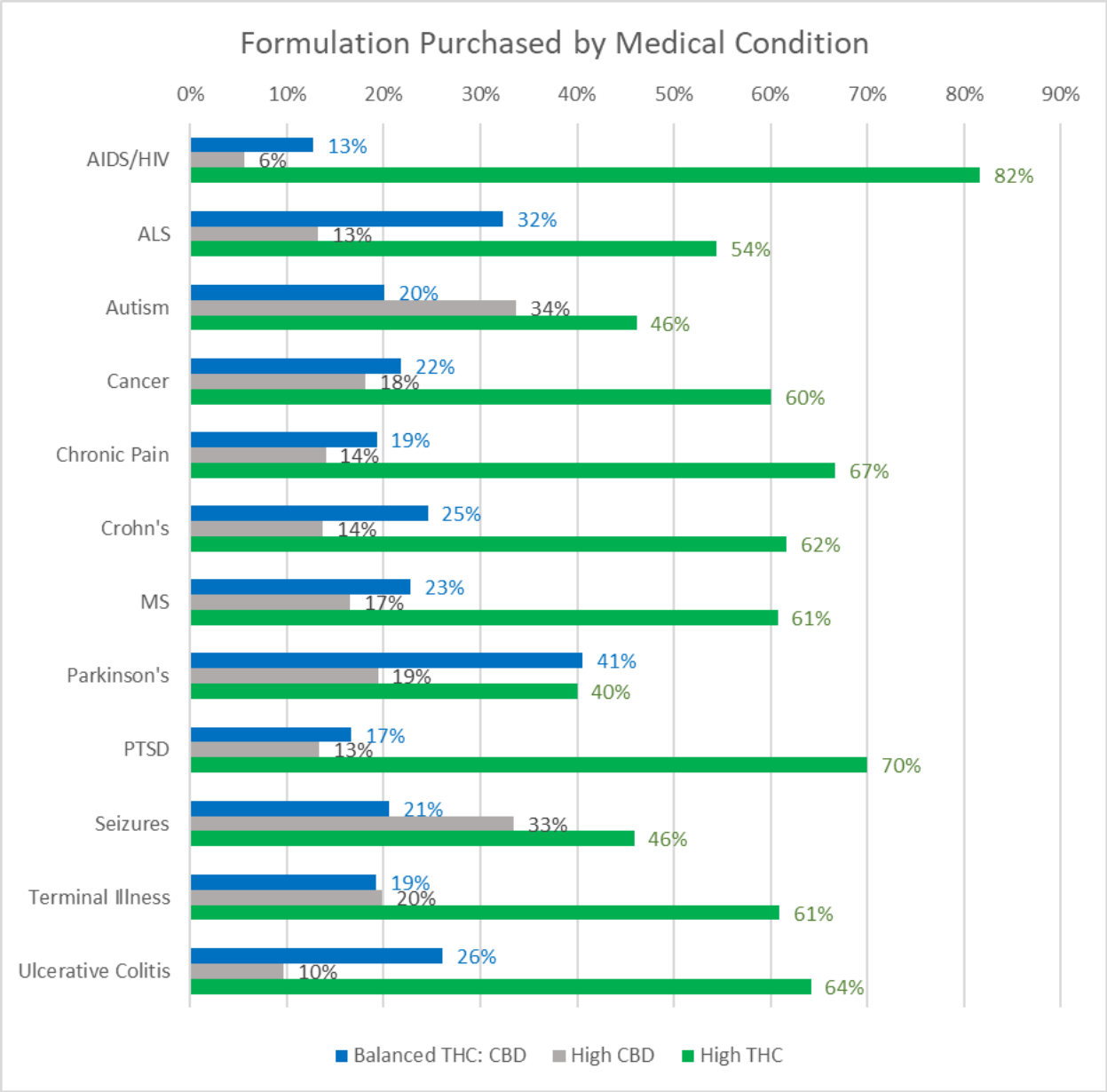


Figure 18 provides percentage-based purchasing behaviors for a given product formulation and qualifying condition.

Figure 18.



VII. Product Testing & Adverse Event Reporting

Product safety and consistency are of paramount importance to the Department. All medical cannabidiol products are tested by the University of Iowa's State Hygienic Laboratory (SHL). During the summer of 2021, the Office of Medical Cannabidiol has run a successful program audit to ensure that every product that is available for sale has been thoroughly tested. 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.

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