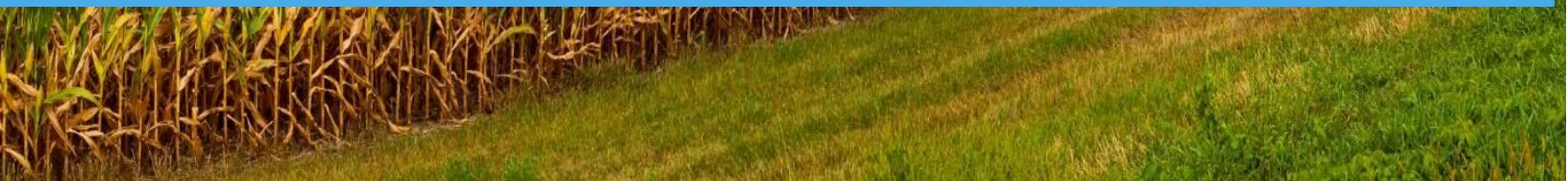




# **2020 Annual Report**

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



**Authorship - Office of the Deputy Director, Bureau of Medical Cannabidiol**

**January 1, 2021**

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

1



## 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<sup>1</sup>:

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<sup>2</sup>.

This report summarizes the Board's activities, recommendations for improvement, program highlights, and program data during calendar year 2020.

The mission of the Office of Medical Cannabidiol (OMC) at the Iowa Department of Public Health is to have a high-quality, effective, and compliant medical cannabidiol program for Iowa residents with serious medical conditions. The OMC works to balance a patient's need for access to treatment of their debilitating medical condition, with the requirement to ensure the safety and efficacy of the products.

The OMC 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 data within the following figures and tables for this report were obtained through December 31, 2020, 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.

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<sup>1</sup> Iowa Code section 124E.5(3)

<sup>2</sup> Iowa Code section 124E.5(6)

## I. Report on Activities of the Board and Program

### Board Meetings

The Board held four meetings during 2020.

1. [February 14, 2020](#)
2. [June 19, 2020](#)
3. [September 14, 2020](#)
4. [November 13, 2020](#)

#### February 14, 2020

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

##### [Medical Cannabidiol Petition Subcommittee Report - February 14, 2020](#)

1. Panic disorder – **Denied (unanimously)**
2. ADHD – **Denied (unanimously)**

The Board received a presentation by Dr. Corey Burchman, Chief Medical Officer of Acreage Holdings, on the benefits of providing wider dosage ranges of THC for patients; the Board also received a similar presentation from Lucas Nelson, General Manager of MedPharm Iowa. Owen Parker, Program Manager, gave a presentation on the status of THC purchasing behaviors among Iowa’s patients. The Board reviewed pending legislation and multiple bills that included Board recommendations from the 2019 Annual Report.

#### June 19, 2020

This meeting was originally scheduled for May 15, but was rescheduled to June 19 due to the COVID-19 pandemic. At its June meeting, the Board considered five petitions for the addition of new qualifying conditions:

##### [Medical Cannabidiol Petition Subcommittee Report - June 19, 2020](#)

1. PTSD, refractory to standard treatment
  - Action was deferred - “post-traumatic stress disorder” was included in HF2589
2. Severe, intractable autism with intractable irritability and aggression, refractory to acceptable standard treatment
  - Action was deferred - “severe, intractable autism with self-injurious or aggressive behaviors” was included in HF2589
3. Generalized anxiety disorder - **Denied (unanimously)**
4. Any rare condition or disease that affects less than 200,000 individuals in the U.S., as defined in federal law, refractory to conventional treatment - **Denied (unanimously)**
5. Tourette syndrome - **Denied (unanimously)**



Owen Parker, Program Manager, provided updates on the closure and relinquishing of licenses by the Have A Heart dispensaries in Council Bluffs and Davenport, and by the Iowa Relief manufacturing facility in Cedar Rapids. Owen also provided updates on RFPs to license two new dispensaries and a manufacturer. At the time of this meeting HF2589, a bill containing nearly all of the Board’s recommendations in their 2019 Annual Report, had passed both chambers of the Iowa Legislature and was awaiting signature by Gov. Reynolds. An update on the Office of Medical Cannabidiol’s response to COVID-19 was also provided.

### **September 4, 2020**

At its September meeting, the Board did not consider any petitions for new qualifying conditions.

Owen Parker, Program Manager, provided an update on the Department’s progress on the implementation of HF2589. The Board received a presentation from Dr. Brian Kaskie, professor and researcher at the University of Iowa College of Public Health, on medical cannabis observational studies he had conducted in other medical cannabis programs. The Board also discussed concerns raised about marketing by licensees, as well as continuing education on medical cannabis that could be provided to Iowa’s certifying healthcare practitioners.

### **November 13, 2020**

At its September meeting, the Board considered one petition for the addition of a new qualifying condition:

#### [Medical Cannabidiol Petition Subcommittee Report - November 13, 2020](#)

1. Pediatric acute-onset neuropsychiatric syndrome (PANS) - **Denied (4-2)**

Owen Parker, Program Manager, led the Board in a discussion about providing accredited medical cannabis continuing medical education (CME) to Iowa’s healthcare practitioners and discussed how the associated licensure boards were supportive of doing so. The OMC identified two providers of these CME services and discussed how they would move forward with providing access to them on the OMC’s website. The Board also discussed recommendations for the 2020 annual report, and how they would like to provide a delivery option to patients in underserved areas, as well remove sales tax from medical cannabidiol products.

### **Making Recommendations for Adding/ Removing Medical Conditions<sup>3</sup>**

The following conditions were added to Iowa’s Medical Cannabidiol Program in 2020:

1. **Chronic pain** – Approved by the Board in August, 2019. Unanimously denied by the Board of Medicine in September, 2019. Added to the list of debilitating qualifying conditions by HF2589 on July 1, 2020.
2. **Post-traumatic stress disorder** - Approved by the Board in November, 2019. Denied by the Board of Medicine in December, 2019. Added to the list of debilitating qualifying conditions by HF2589 on July 1, 2020.
3. **Severe, intractable autism with self-injurious or aggressive behaviors** - Approved by the Board in April, 2019. Denied by the Board of Medicine in December, 2019. Added to the list of debilitating qualifying conditions by HF2589 on July 1, 2020.

## **II. 2020 Recommendations of the Board to the Iowa General Assembly**

### **1. Allowing for Home or Satellite-Delivery**

The Board recommends dispensaries be provided with the ability to transport or deliver medical cannabidiol to patients to increase patient access to medical cannabidiol products in areas of Iowa that are underserved due to the small number of licensed dispensaries. Currently, chapter 124E does not provide the necessary affirmative defenses for dispensary staff to transport medical cannabidiol. Any amendments to the statute to allow transport or delivery of medical cannabidiol products by dispensaries would need to amend the affirmative defense provisions as well.

### **2. 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.

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<sup>3</sup> Iowa Code section 124E.5(3)(b)



### III. Passage and Implementation of HF2589

The passage of [HF2589](#), made material changes to Iowa’s program. HF2589 contained all but one of the recommendations made by the Medical Cannabidiol Board in their [2019 Annual Report](#), including:

1. **Removal of the 3% THC limit in final medical cannabidiol product formulations, and movement to “4.5g THC per 90 days,” with exceptions:**
  - a. **For the terminally ill;**
  - b. **Or if the patient’s certifying healthcare practitioner certifies them for greater than 4.5g THC per 90 days**

The OMC has created a “[4.5g THC Waiver Form](#)” that a patient’s healthcare practitioner may complete for patients who are already participating in the program. This form is modeled after similar forms and processes in other state medical cannabis programs. Since July 1, 5.2% of the registered patients have received THC purchase cap waivers from their providers.

2. **Adds physician assistants (PAs), advanced registered nurse practitioners (ARNPs), and podiatrists (DPM) to the list of healthcare practitioners who can certify a patient’s condition for the use of medical cannabidiol.**

The OMC communicated with the licensure boards of the new disciplines who are able to certify patients under HF2589. The OMC has seen participation by all these new disciplines; please see Figure 2 for related data. The OMC is also working with multiple vendors who provide medical cannabis continuing medical education (CMEs), and will have Iowa-specific and core curriculum courses available to Iowa’s healthcare practitioners on its website in early 2021.

3. **Requires that dispensaries employ either a pharmacist or pharmacy technician.**

The OMC has verified that all dispensaries employ either a pharmacist or pharmacy technician to aid in the titration schedule and selection of medical cannabidiol products of patients.

4. **Removal of the Department of Transportation (DOT) from the Registration Card Process, and charge IDPH with the issuance of registration cards.**

On July 1, the effective date of HF2589, the Department began issuing medical cannabidiol registration cards to patients and caregivers. This has removed a significant burden to patients, and has led to significantly faster time from application submission to patient enrollment in the medical cannabidiol program.

5. **Charges IDPH to seek protections for schools, and long-term and acute care facilities who receive federal funding.**

The Department is still evaluating the best way to proceed with implementation of the section requiring IDPH to "request guarantees from agencies of the federal government providing funding to educational and long-term care facilities that facilities with policies allowing patients to possess medical cannabidiol on the grounds of the facilities ... shall not lose eligibility for any federal funding due to such policies."

**6. Movement to a “Total THC” Calculation for Determination of Product Potency**

The Department has collaborated with the State Hygienic Laboratory at the University of Iowa to ensure that this requirement is implemented into final product testing, and is reflected in [v4.3 of the Laboratory Testing Requirements & Acceptance Criteria Document](#) as described in 641 Iowa Administrative Code (IAC) chapter 154.69(1).

**7. Allows the Department to conduct an observational study with patients and caregivers.**

The Board discussed conducting an observational study at its September meeting. No final decisions have been made.

**8. Removal of the Felony Disqualifiers for Patients and Caregivers.**

**9. Provide physician access to the patient registry for the purposes of determining if the patient has already been certified by a different healthcare practitioner.**

**10. Allows the Board to meet more than four times per year, if necessary.**

#### **IV. Office of Medical Cannabidiol COVID-19 Response**

In response to COVID-19, the Department took several measures to continue to provide patient access to medical cannabidiol, including:

1. Provided an administrative rule waiver to allow for on-camera, curbside dispensing of medical cannabidiol at licensed dispensaries.
2. Worked with the DOT to schedule socially-distanced appointments with patients and caregivers.
3. Encouraged and facilitated telemedicine.

A significant percentage of qualifying patients are at high risk for COVID-19. The OMC provided a waiver for on-camera, curbside dispensing to allow dispensary sales to continue in a socially-distanced and safe manner while still ensuring regulatory compliance and security.

The OMC worked with the Iowa DOT to prioritize registration card issuance appointments for new patients. For patients renewing their registration, the DOT was able to mail registration cards to patients, as opposed to in-person appointments at a DOT office.

Administrative rules do not prohibit telemedicine to certify or recertify a patient's condition. The OMC worked with patients and providers to facilitate consultations via telemedicine, as opposed to a physical visit with the patient's healthcare practitioner.

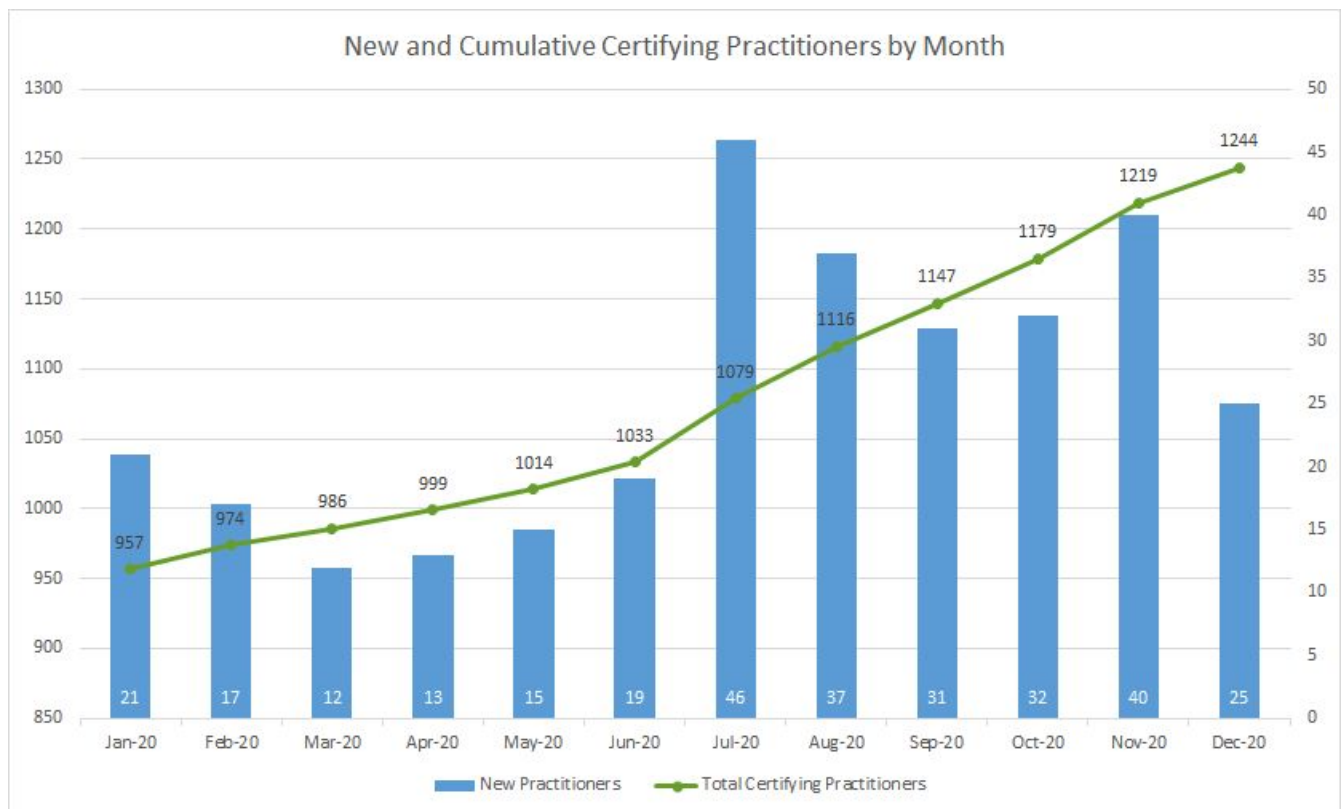
## V. 2020 Program Data

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.

### 1. Healthcare Practitioners

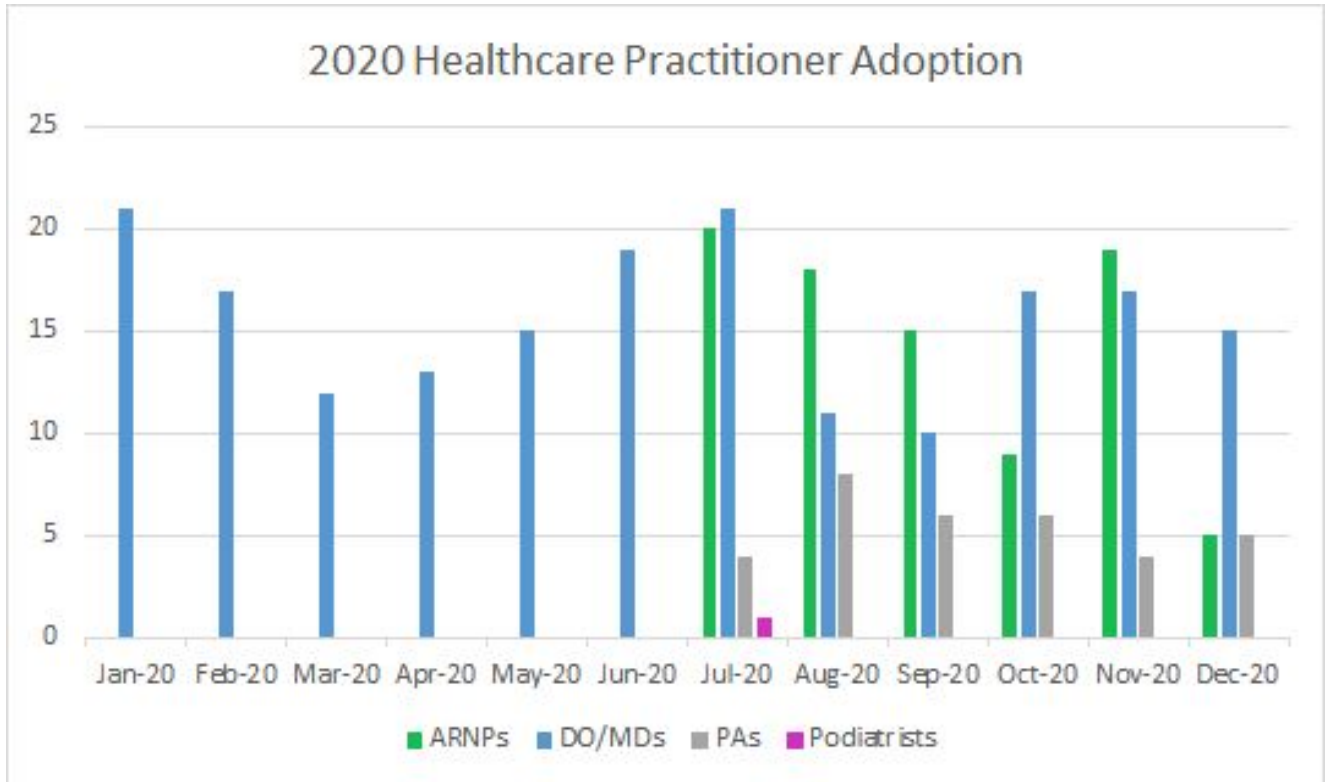
Healthcare practitioners are not required to complete specific training on medical cannabis prior to certifying a patient for the Iowa Medical Cannabidiol Program. A healthcare practitioner is defined as a physician (MD/DO), physician assistant (PA), advanced registered nurse practitioner (ARNP), or 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 were not allowed to certify patients.

**Figure 2.**

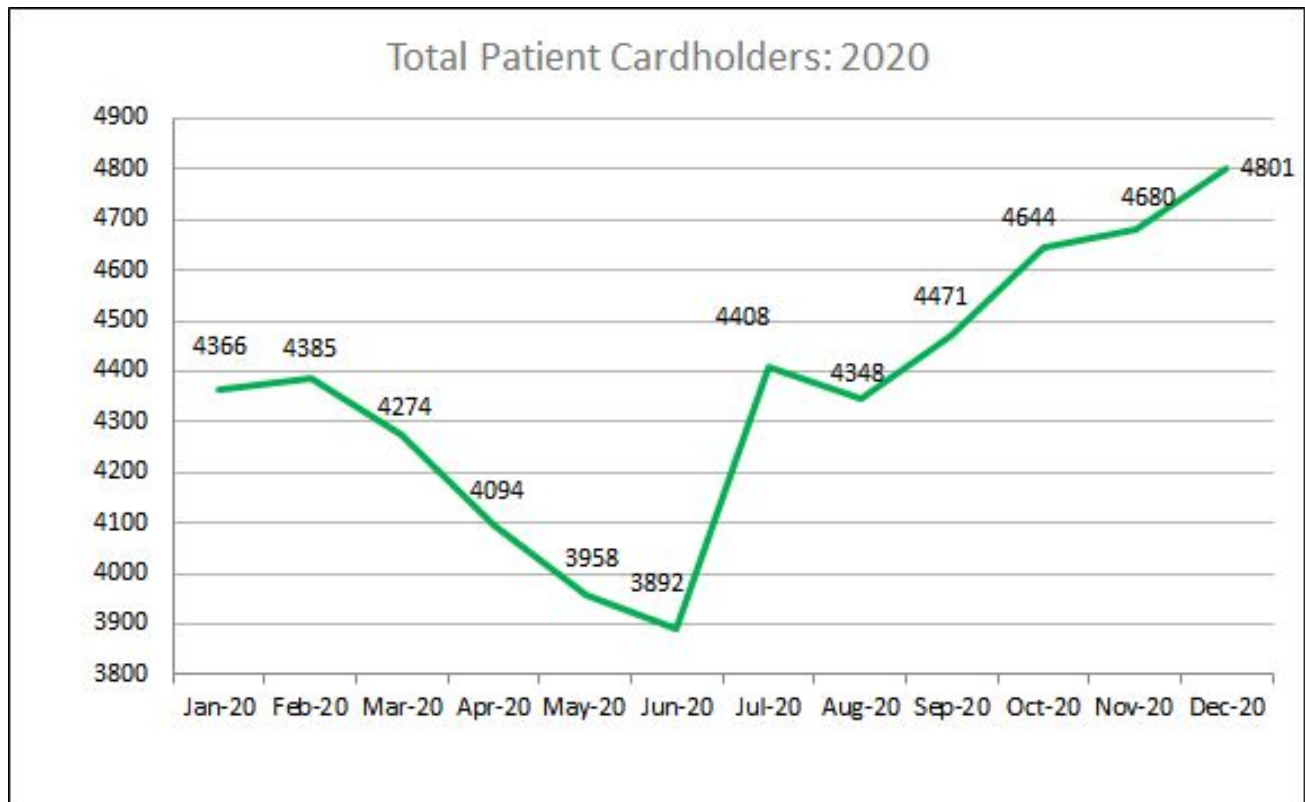


## 2. Patients and Caregivers

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.

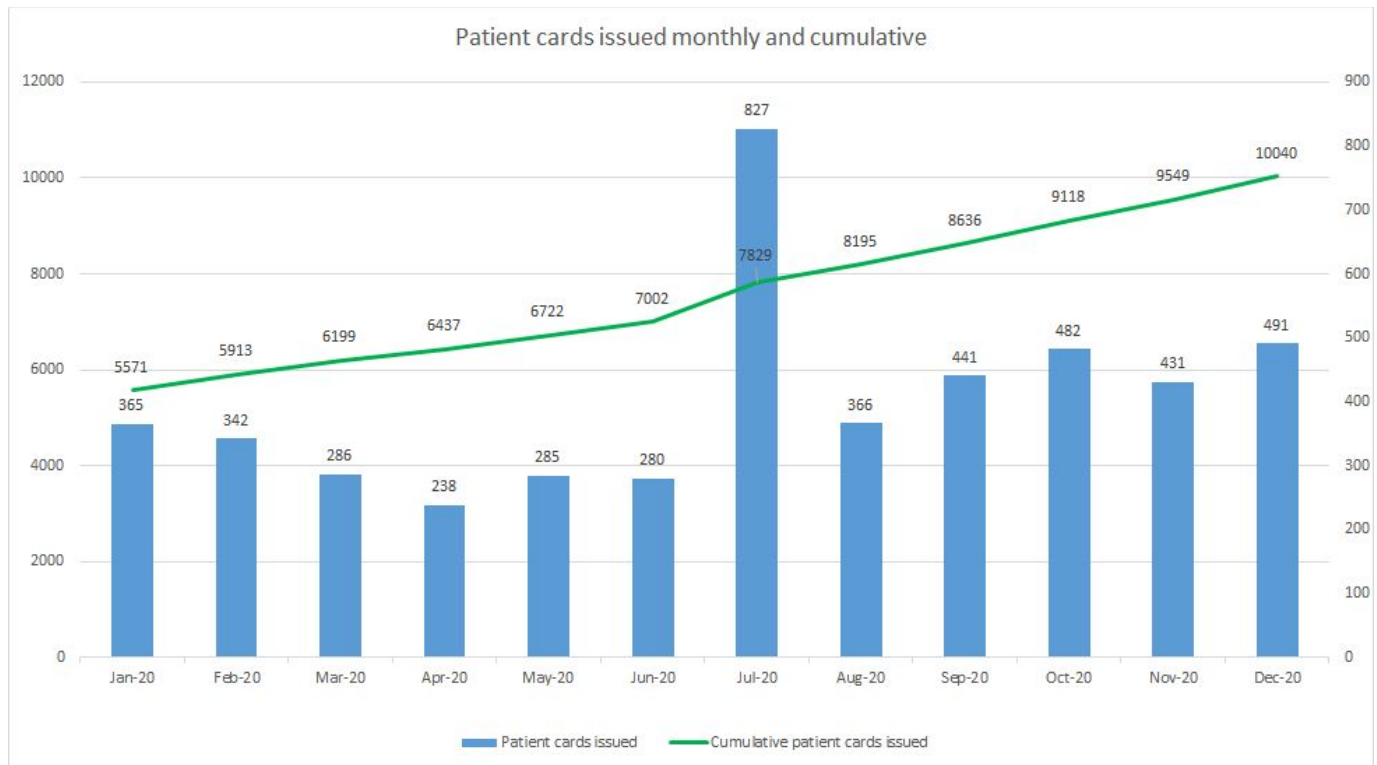
**Figure 3** depicts the number of patients with active registration cards in each month of 2020. Prior to July 1, 2020 registration cards were issued by the Iowa Department of Transportation. IDPH began issuing cards on July 1, 2020.

**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.

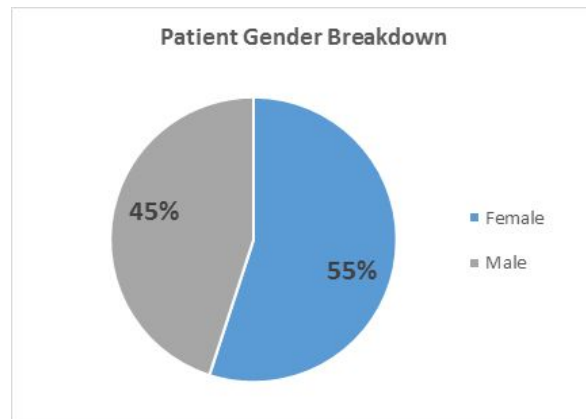
Age	AIDS/HIV	ALS	Autism	Cancer	Chronic Pain	Crohn's	MS	Parkinson's	PTSD	Seizures	Terminal Illness	Ulcerative Colitis	Total
10 or under			55	3	4		2		2	18	1		85
11 - 17			31	3	4		1		3	15			57
18 - 30	2	1	19	9	181	21	6	1	59	42	1	9	351
31 - 40	3		2	30	483	23	35	1	77	25	2	11	692
41 - 50	9	2	1	46	629	22	49	6	46	22		7	839
51 - 60	7	3	1	69	844	11	56	16	28	12	3	6	1056
61 - 70	6	3		119	737	8	42	35	12	11	5	7	985
71 - 80		1		60	379	7	7	43	5	7	4	1	514
81 - 90				14	125		1	19	1	2	4		166
Over 90				4	19			2			2		27
<b>Total</b>	<b>27</b>	<b>10</b>	<b>109</b>	<b>357</b>	<b>3405</b>	<b>92</b>	<b>199</b>	<b>123</b>	<b>233</b>	<b>154</b>	<b>22</b>	<b>41</b>	<b>4772</b>
<b>% of Total</b>	<b>0.57%</b>	<b>0.21%</b>	<b>2.28%</b>	<b>7.48%</b>	<b>71.35%</b>	<b>1.93%</b>	<b>4.17%</b>	<b>2.58%</b>	<b>4.88%</b>	<b>3.23%</b>	<b>0.46%</b>	<b>0.86%</b>	

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.

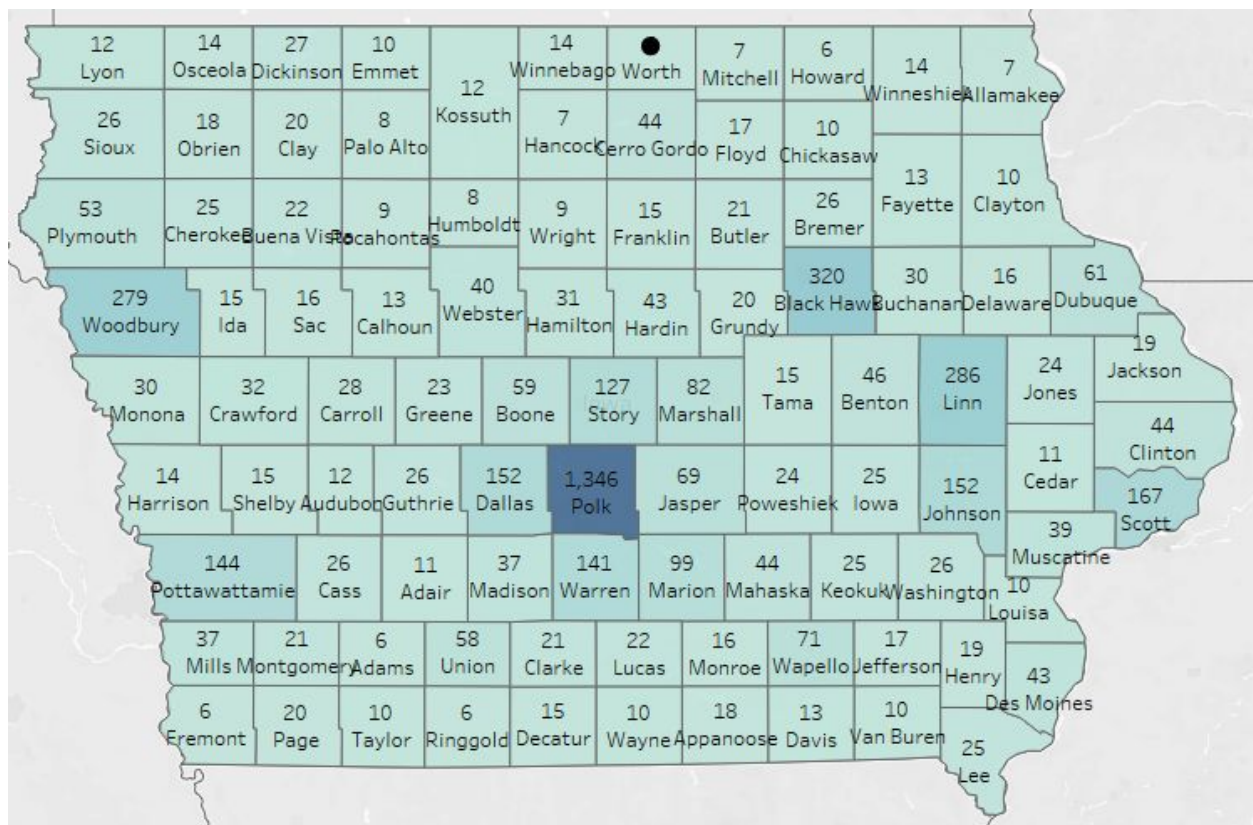
**Figure 6.**



**Figure 7** represents the density of active registration card-holders by county in Iowa.

**Figure 7.**

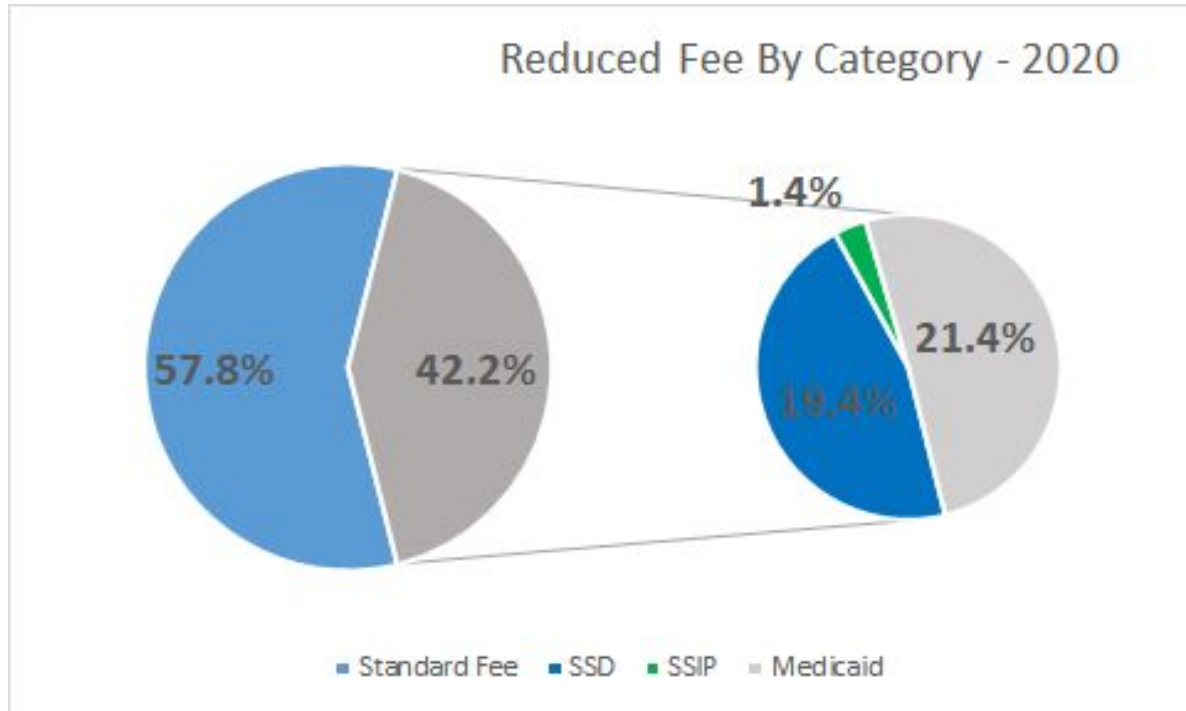
### Medical Cannabidiol Registration Card-holders by County



Note: Values of < 5 are indicated by \*

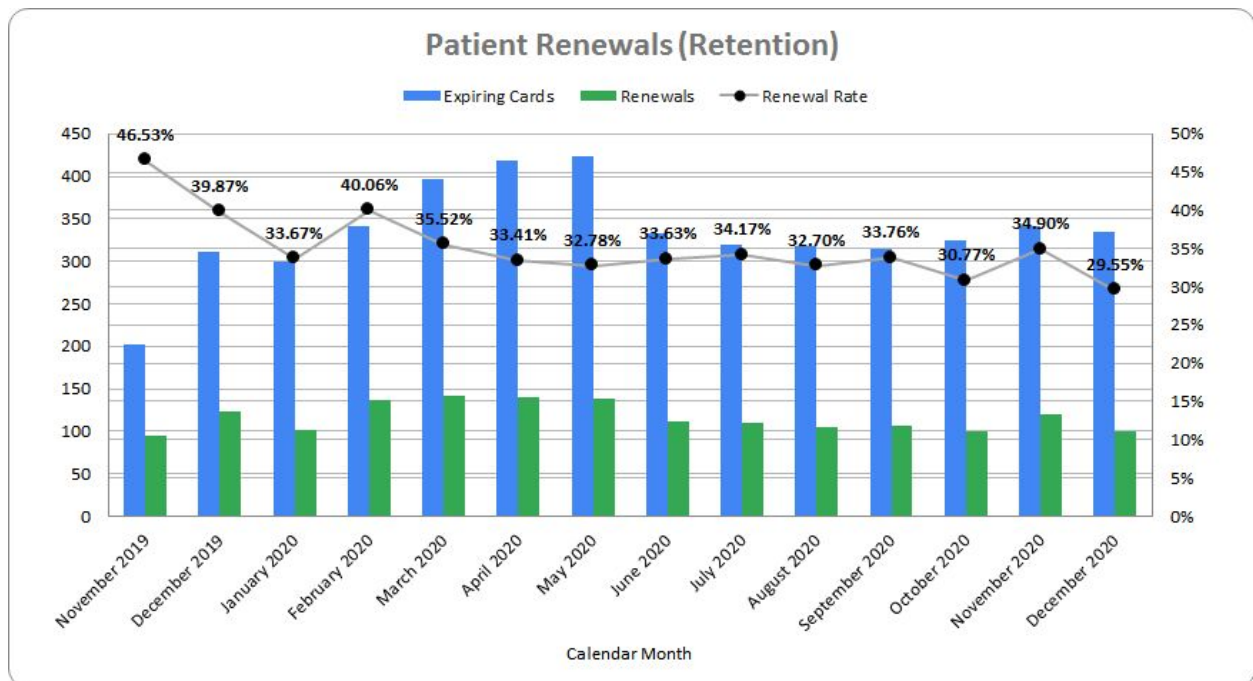
Patients in Iowa are eligible for a reduced fee when applying for their medical cannabidiol registration card. If a patient can provide proof of Social Security Disability Insurance (SSDI), Supplemental Security Income (SSI), or Medicaid, they are eligible for a reduced fee. **Figure 8** depicts the percentage of standard (\$100) or reduced (\$25) fee applications, as well as the percentage of each reduced fee type.

**Figure 8.**

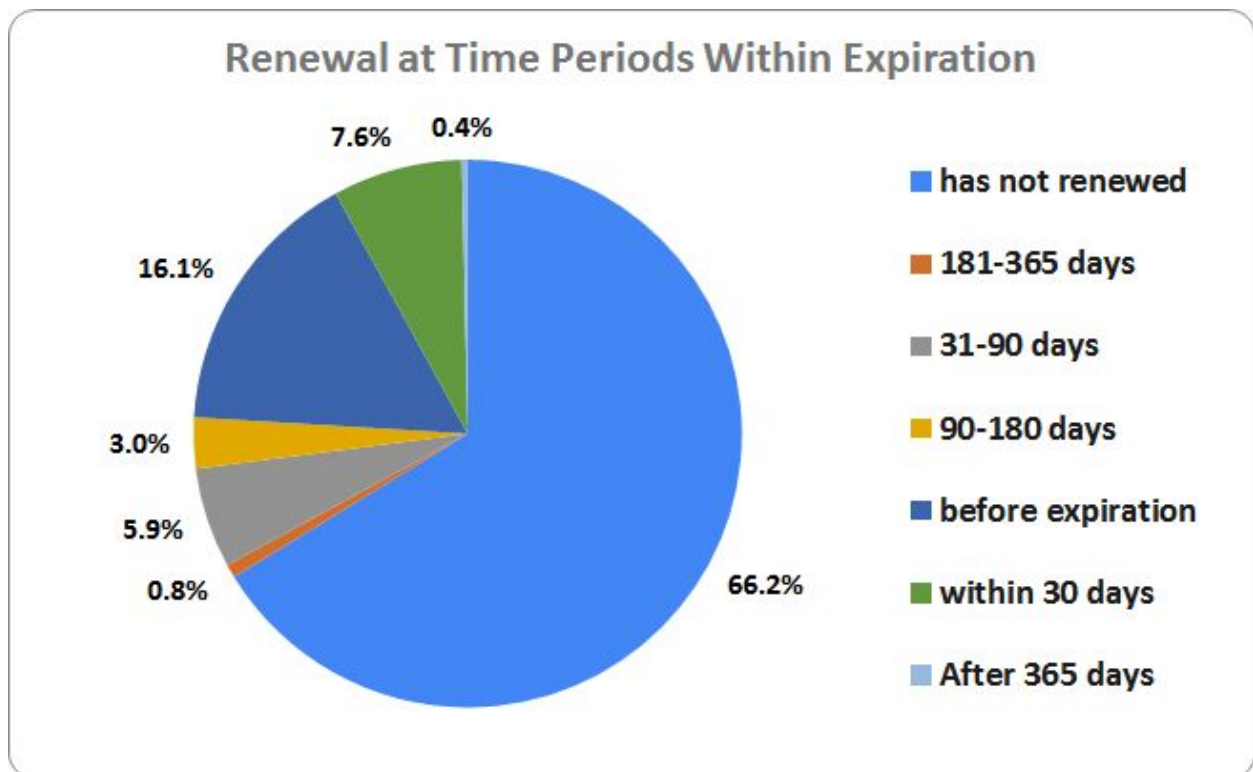


A patient's medical cannabidiol registration card is valid for one year from the date of issuance. **Figure 9** represents the number of cards expiring each month as compared to the number of renewal applications and the monthly renewal rate.. **Figure 10** represents patient renewals at different time periods within card expiration.

**Figure 9.**

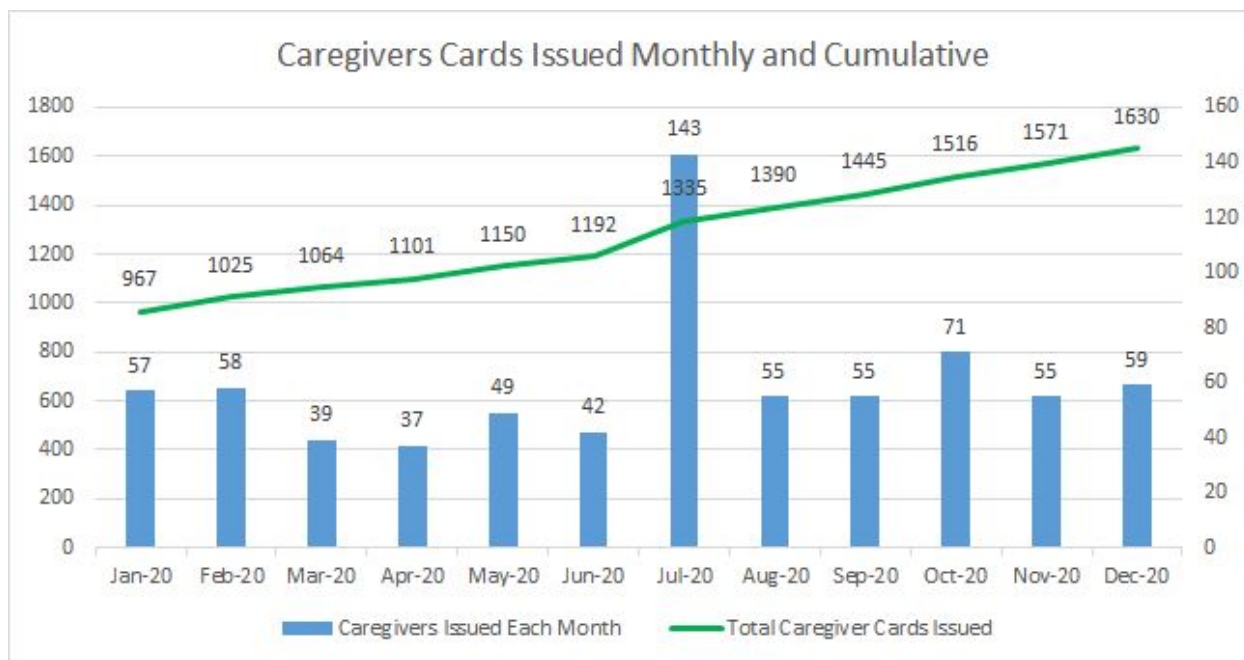


**Figure 10.**



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 11** 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 11.**



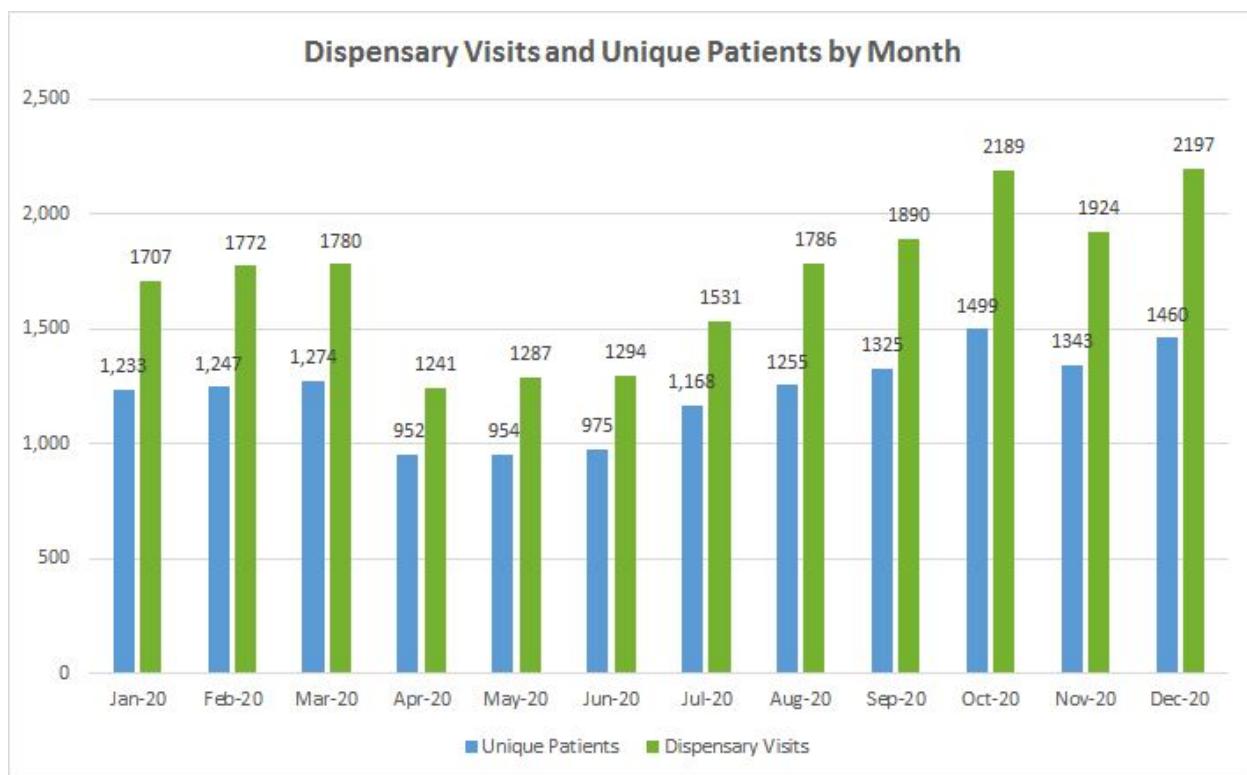
### 3. Dispensary Sales

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.

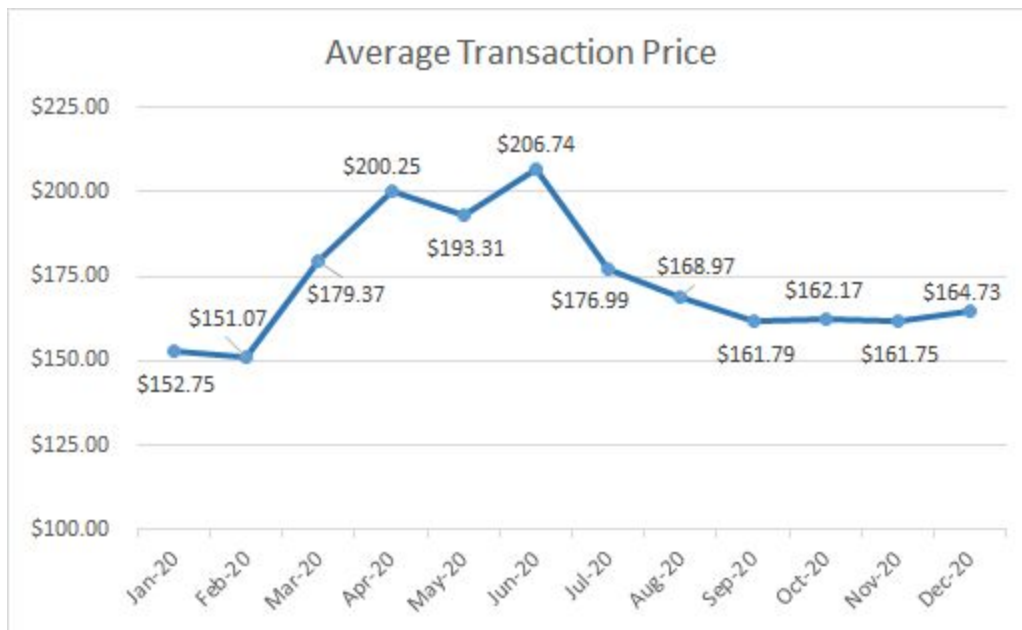
**Figure 12** depicts the number of unique patients who visited a dispensary in a given month in 2020, as well as the total dispensary visits each month during 2020.

**Figure 12.**



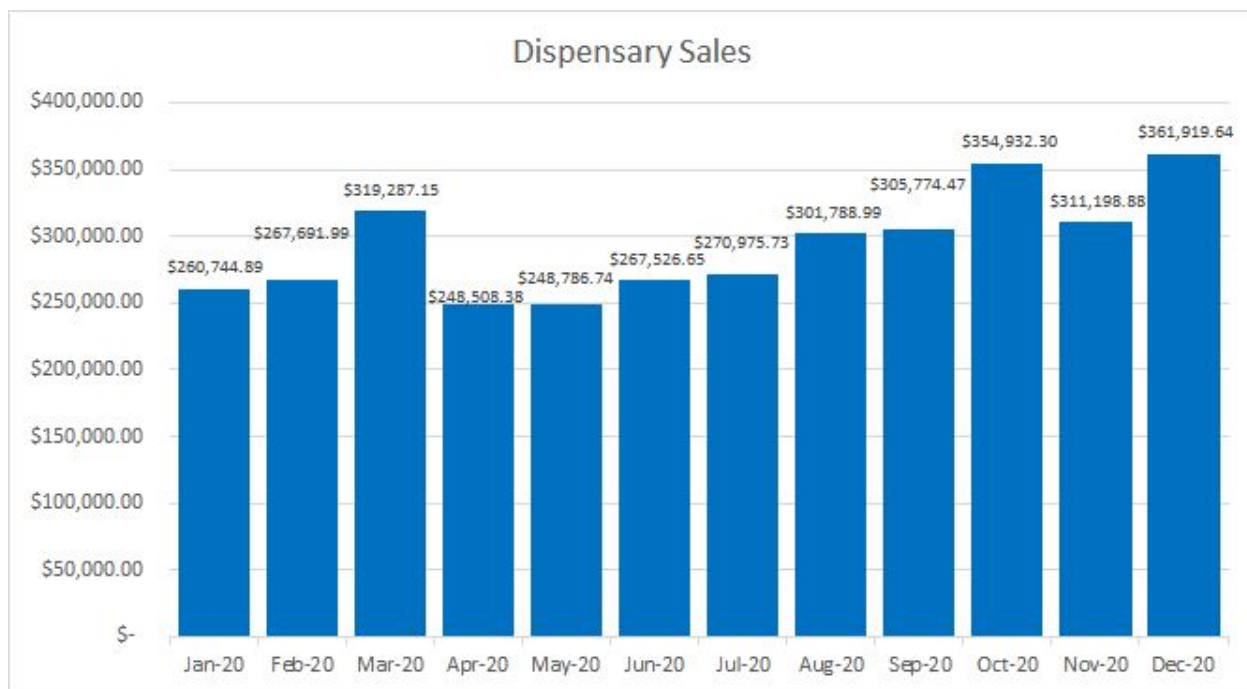
**Figure 13** represents the average transaction price (excluding tax) amongst Iowa’s licensed dispensaries during 2020.

**Figure 13.**



**Figure 14** 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 14.**

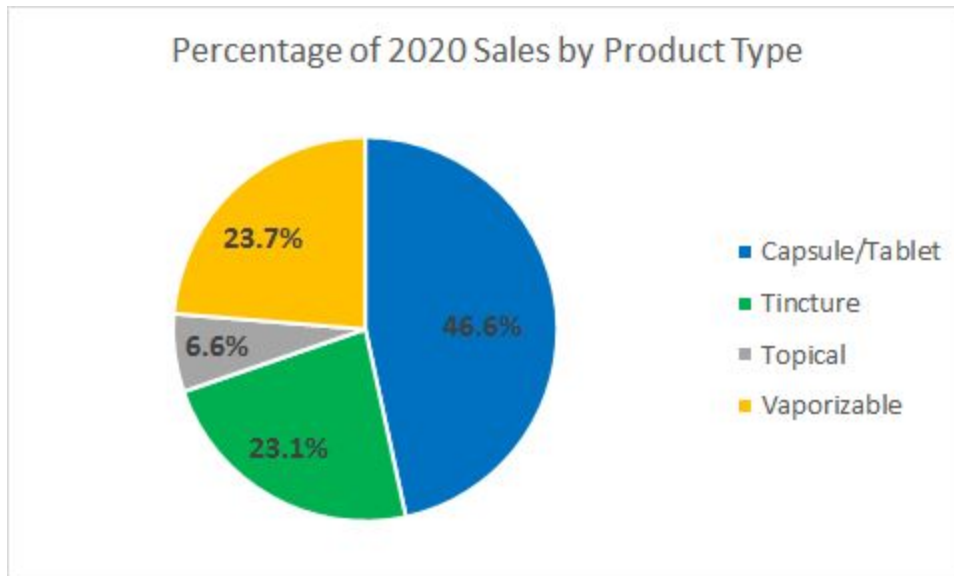




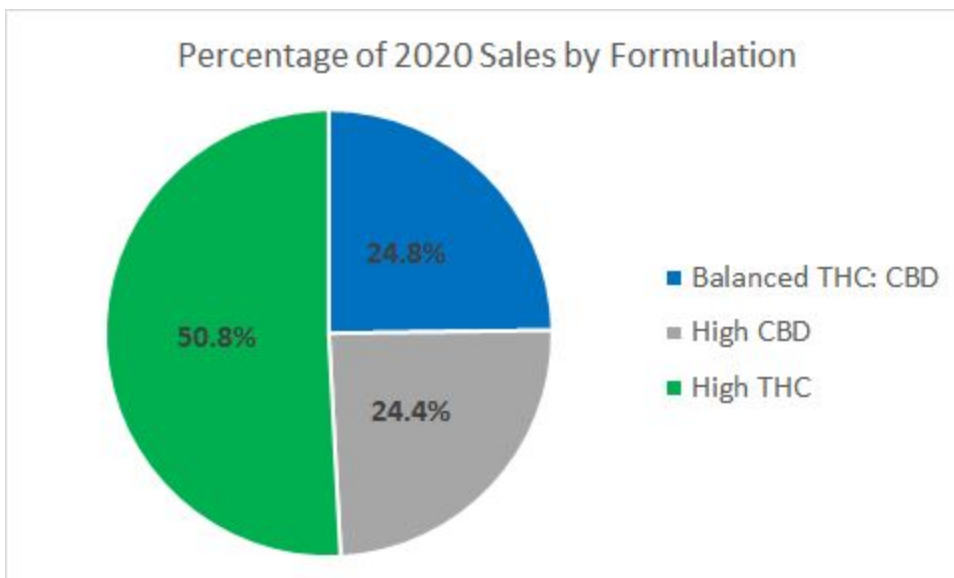
Chapter 124E allows Iowa’s two licensed manufacturers to manufacture products in the following forms: oral forms (tinctures, capsules, tablets and sublingual forms), topical forms (gels, ointments, creams, lotions and transdermal patches), nebulizable forms, suppository forms and vaporized forms (vaporized forms became available for sale on August 7, 2019).

**Figures 15 & 16** depict the percentage of product sales in 2020 by formulation and product type.

**Figure 15.**



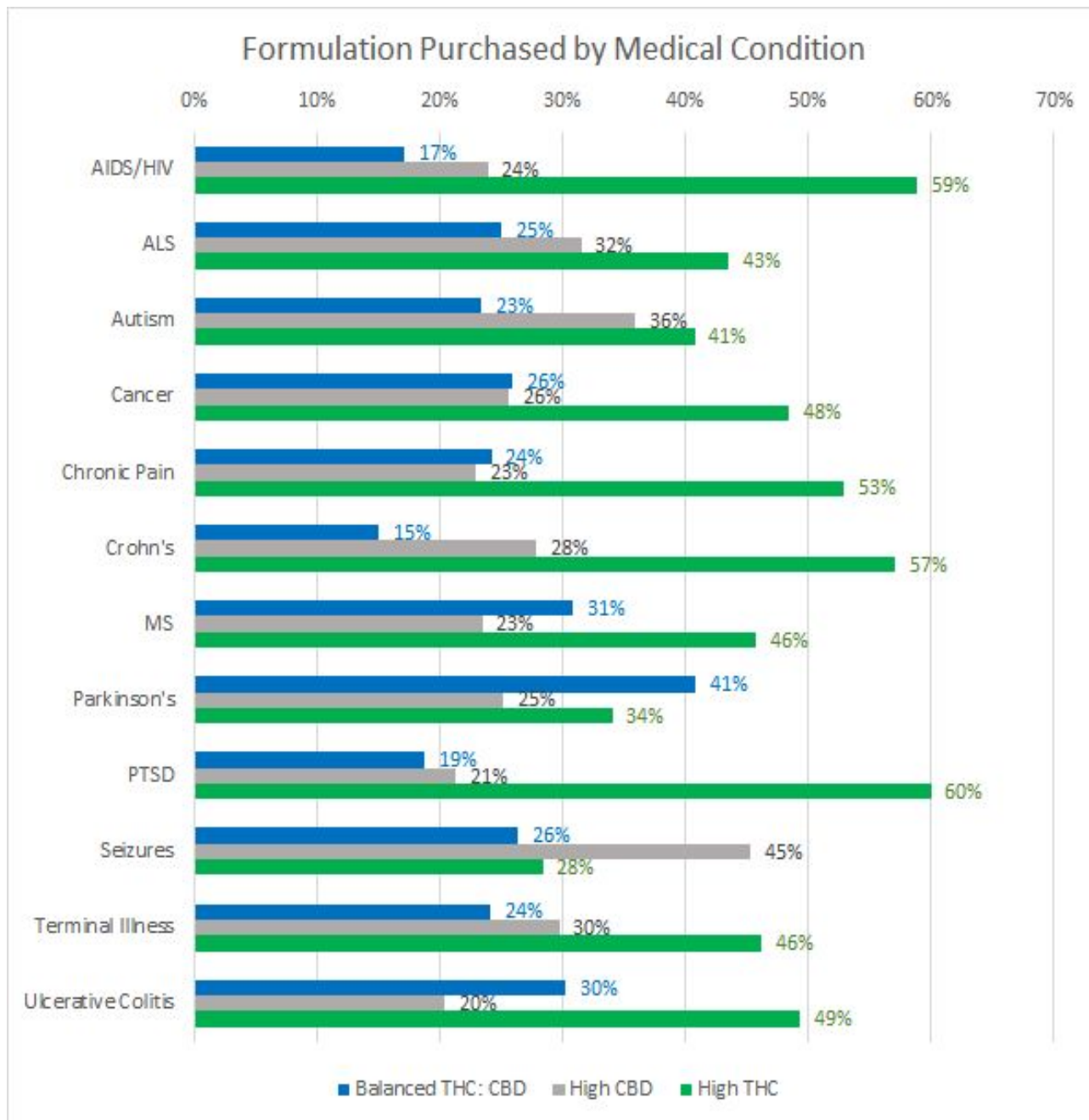
**Figure 16.**





**Figure 17** provides percentage-based purchasing behaviors for a given product formulation and qualifying condition.

**Figure 17.**



## VI. 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 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 Office of Medical Cannabidiol’s website.