

Delaware Medical Marijuana Program Annual Report





Delaware Medical Marijuana Program Annual Report

Fiscal Year 2022

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https://dhss.delaware.gov/dhss/dph/hsp/medmarhome.html

December 2022



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Delaware Medical Marijuana Program Annual Report

Program Year 10

July 1, 2021 - June 30, 2022 (State Fiscal Year 2022)

I. Executive Summary

According to published research, there is supporting evidence that the use of medical marijuana alleviates chronic neuropathic or cancer pain; reduces the use of opioids and analgesic enhancement for long-term pain management; lessens spasticity; and reduces nausea, vomiting, and weight loss associated with chronic debilitating conditions.¹ Marijuana is a psychoactive drug derived from the Cannabis sativa plant. Three primary compounds in cannabis are associated with health benefits. Some studies indicate that Tetrahydrocannabinol (THC) activates pathways in the central nervous system, which blocks pain signals to the brain.² THC is known to reduce nausea and stimulate appetites in both healthy and sick individuals. The medical effects of Cannabidiol (CBD) are anti-inflammatory, anti-pain, anti-anxiety, anti-psychotic, and anti-spasm effects without disconcerting lethargy or dysphoria. Scientific and clinical studies of CBD tie it to treatment for a wide range of conditions, including multiple sclerosis, rheumatoid arthritis, diabetes, alcoholism, chronic pain, schizophrenia, Post Traumatic Stress Disorder (PTSD), antibiotic-resistant infections, epilepsy, and other neurological disorders.¹ THC acid (THC-A) provides many of the same neurogenic and neuro-protectant benefits as Cannabidiol when used in a capsule or oil.³

To regulate the medical use of marijuana, the Delaware General Assembly passed Senate Bill 17, the Delaware Medical Marijuana Act, in May 2011. Governor Jack Markell signed the Delaware Medical Marijuana Act on May 13, 2011, and it became effective on July 1, 2011. It is now enabled in Title 16^4 , Chapter 49a of the Delaware Code.

The Delaware Department of Health and Social Services (DHSS), Division of Public Health (DPH) is charged with implementing the Delaware Medical Marijuana Act that regulates the medical use of marijuana in Delaware. DPH's Office of Medical Marijuana (OMM) operates the Delaware Medical Marijuana Program (MMP). This report documents the MMP's growth, challenges, accomplishments, and activities during its tenth year, State Fiscal Year 2022 (FY22). This report is submitted as required by paragraph §4922A (b)⁵ of the Delaware Medical Marijuana Act.

¹ <u>Top Studies Proving Medical Marijuana</u> Works (cannamd.com)

² Greenwell GT. Medical marijuana use for chronic pain: risks and benefits. J Pain Palliat Care Pharmacother. 2012;26(1):68-9. doi: 10.3109/15360288.2011.652350. PMID: 22448949.

https://www.ncbi.nlm.nih.gov/books/NBK425767/

⁴ http://delcode.delaware.gov/title16/c049a/index.shtml

⁵ http://delcode.delaware.gov/title16/c049a/index.shtml

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This report provides the progression of the MMP with details including:

- 1. The number of applications and renewals filed for registry identification cards.
- 2. The number of qualifying patients and designated caregivers approved in each county.
- 3. The nature of the debilitating medical conditions of the qualifying patients.
- 4. The number of registry identification cards revoked for misconduct.
- 5. The number of physicians providing written certifications for qualifying patients.
- 6. The number of registered compassion centers.
- 7. An accounting of fees and costs.

Through OMM's series of annual reports, constituents and other state MMPs can follow the development of the medical marijuana industry in Delaware to understand the milestones and benchmarks. This report and the preceding annual reports are posted to the MMP website, under the Medical Marijuana Oversight Committee tab, at

https://dhss.delaware.gov/dhss/dph/hsp/medmaroc.html.

The Delaware Medical Marijuana Act only permits the sale of medical marijuana from dispensaries named Compassion Centers. There are six Compassion Center companies in Delaware. DPH contracts with the companies that own the Compassion Centers to both grow and sell medical marijuana in the state.

In June 2015, Delaware opened its first medical marijuana dispensary, the First State Compassion Center (FSCC) in Wilmington. The grow facility is also located in Wilmington. In December 2015, DHSS published a request for proposals (RFP) to establish, open, and operate two new compassion centers, one each in Kent and Sussex counties. DHSS awarded contracts in September 2016 to Columbia Care for Kent County and in October 2016 to the FSCC for Sussex County. FSCC in Sussex opened their Lewes location in May 2017, using product grown in their Wilmington cultivation facility. Columbia Care opened their cultivation site in Milford and their dispensary in Smyrna at the end of June 2018. Acting on the advice of the Oversight Committee, the MMP offered Compassionate Care Research Institute (CCRI) a contract to make more product available to the patients in New Castle County due to a greater level of demand based on the size of the patient population. CCRI opened their retail operation there in March 2019. In January 2020, Columbia Care was permitted to open retail locations in New Castle County and Sussex County to ease congestion at the other locations. In September 2020, a Request for Applications (RFA) HHS 20-016 was released to add additional capacity. Three venders were chosen, Canntech Research, EZCure and Valor Cannabis. EZCure, operating as "The Farm" opened a retail location in Felton, DE in August 2021. Further information and locations of Delaware's Compassion Centers can be found at https://dhss.delaware.gov/dph/hsp/medmarcc.html.

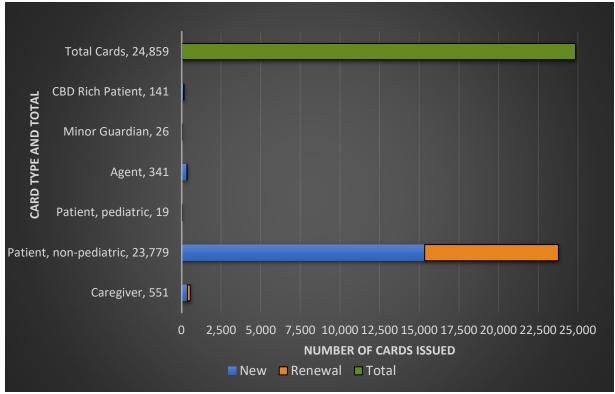
Across the United States, the landscape of marijuana or cannabis laws has continually changed. As of February 3, 2022, 37 states, three territories and the District of Columbia allow the medical use of cannabis products. As of February 3, 2022, 20 states, two territories, and the District of Columbia allow marijuana sales for recreational uses. For the most current information on the rapidly changing status of marijuana laws nationwide, refer to the National Conference of State Legislatures website: https://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx.

II. Overview

Only individuals who are issued a medical marijuana card via the Delaware Medical Marijuana Program (MMP) may purchase medical marijuana at a Compassion Center. During FY22, the Delaware Department of Health and Social Services (DHSS), Division of Public Health's (DPH) Office of Medical Marijuana (OMM) issued 24,859 registration cards, 17% more than the 20,630 issued in State Fiscal Year 2021 (FY21). As depicted in Figures 1 and 2, FY22's cards are categorized as follows:

- 15,334 new patient cards (2021: 12,918)
- 8,445 patient renewal cards (2021: 6,675)
- 360 new caregiver cards (2021: 358)
- 191 caregiver renewal cards (2021: 204)
- 11 new pediatric cards (2021: 13)
- Eight pediatric renewal cards (2021: 10)
- 16 new Minor Guardian cards (2021: 23)
- Ten renewal Minor Guardian cards (2021: 20)
- 339 new agent cards (2021: 272)
- Two renewal agent cards (2021: 137)
- Two Compassionate Use Patient and Caregiver Cards (2021: 0)
- 141 CBD Rich Patient (2021: 56)

Figure 1. Medical Marijuana Program Cards Issued by Type, Delaware, Fiscal Year 2022



Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2022

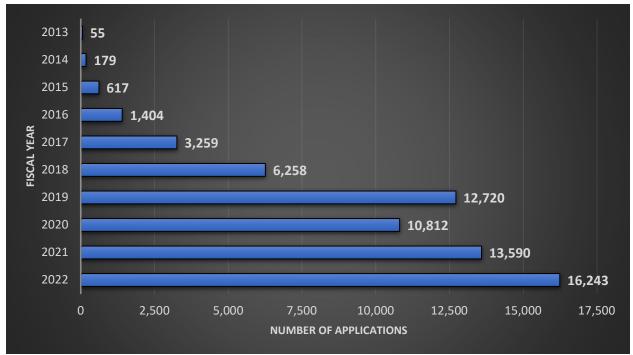


Figure 2. Total Medical Marijuana Program Applications by Fiscal Year, Delaware, Fiscal Years 2013-2022

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2022

The Delaware Medical Marijuana Act requires revenue from the MMP to cover program expenses. In FY22, MMP spent \$516,440 on personnel and the costs of necessary equipment and supplies (Table 1).

Table 1. Office of Medical Marijuana Program Revenue, Delaware, Fiscal Years 2021 and 2022

State Fiscal Year	Revenue	Expenses	Program Net
2021	\$1,099,878	\$564,800	\$535,078
2022	\$1,059,551	\$516,440	\$543,111

Source: State of Delaware, First State Financials System (FSF)

Application Revenue

OMM uses the reduced-fee policy outlined in DHSS Policy Memorandum 37, updated with revised figures from the federal poverty guidelines. The reduced fee is 50% of the full fee, equaling \$25 a year for qualifying low-income participants. In 2022, 94% of the applicants (14,758) paid the full fee. Just over 6% (971) were approved for reduced fee waivers. (Table 2.)

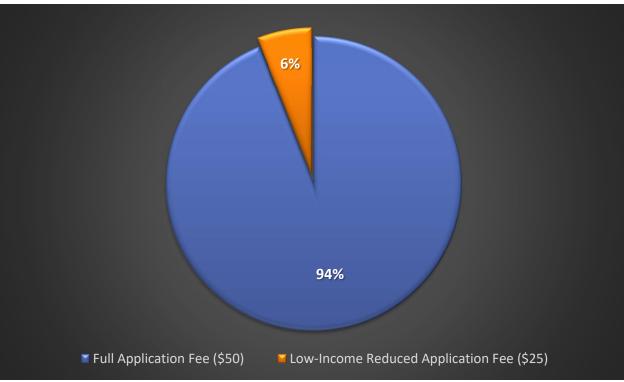
Table 2. Number and Percentages of Medical Marijuana Fees Collected, Delaware, Fiscal Years 2021 and 2022

State Fiscal Year	Full Fee \$50		Reduced F	ee \$25
2021	11,920	92%	1,036	8%
2022	14,758	94%	971	6%

Source: State of Delaware, First State Financials System (FSF)

In Fiscal Year 2022, 94% of the applications received included the full \$50 application fee (Figure 3). Six percent included a low-income charge request for the \$25 application fee.

Figure 3. Number of Medical Marijuana Applications Approved by Amount of Fees Paid, Delaware, Fiscal Year 2022



Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database

III. Education and Outreach

While providing medicinal marijuana to patients is the most visible aspect of the MMP, an equally important aspect is to educate and inform stakeholders in a variety of settings and on a wide range of topics. Stakeholders include patients, law enforcement, advocates, and the medical community. The program receives many inquiries and requests for clarification on issues or procedures. OMM normally handles these issues over the phone or through the MMP website:

http://dhss.delaware.gov/dhss/dph/hsp/medmarhome.html. To address deeper issues or larger groups, the program does community outreach briefings.

Inquiry Response

There are multiple ways stakeholders and constituents can ask questions about the MMP. There is a dedicated program phone number, 302-744-4749, and an e-mail address:

MedicalMarijuanaDPH@Delaware.Gov. In conjunction with DPH's Office of Communications, OMM developed Frequently Asked Questions (FAQ) for patients, physicians, and law enforcement. The FAQs

developed Frequently Asked Questions (FAQ) for patients, physicians, and law enforcement. The FAQs inform the stakeholders about application requirements for the program, qualifying debilitating medical conditions, details about the compassion center where patients can purchase medical marijuana, possession limits, caregiver responsibilities, and other protections, restrictions, and limitations. In the past two fiscal years, the OMM website averaged over 4,200 unique page views per month (Figure 4).

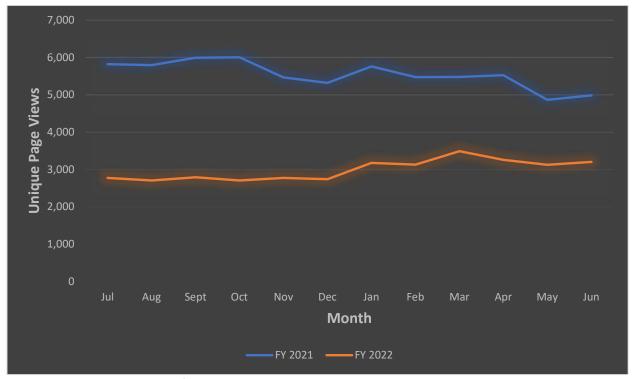


Figure 4. Number of Medical Marijuana Website Hits by Month, Delaware, Fiscal Years 2021 and 2022

Source: Delaware Department of Health and Social Services Internet site Internal Resource Management statistics, Fiscal Years 2021 and 2022.

Community Outreach

The topic of medical marijuana is still controversial in many professional circles; some medical professionals and law enforcement officials have concerns about the safety or efficacy of medical marijuana. To address common misconceptions, MMP Administrator Paul Hyland conducted three briefings and presentations to civic groups and medical practices in FY22.

- The OMM focused on the public safety issue of Delta-8 tetrahydrocannabinol (THC) derived from hemp cannabidiol (CBD). OMM hosted several meetings on the topic with the Delaware Department of Agriculture and Safety and Homeland Security (DSHS) and briefed the Medical Marijuana Act Oversight Committee.
- In March 2022, OMM participated in the DSHS Impaired Driving Strategic Plan working group for "Prevention". OMM will continue to contribute information to develop public awareness campaigns about driving under the influence.

IV. Legislative

In February 2022, the Joint Legislative Oversight and Sunset Committee (JLOSC) initiated legislation to sunset the Medical Marijuana Act Oversight Committee. The 151st General Assembly passed Concurent Resolution #103 which required OMM to create a "Stakeholder Group" to discuss medical marijuana issues in Delaware. Two public meetings of the "Stakeholder Group" will be scheduled and held during the first two quarters of the 2023 fiscal year.

In May 2022, OMM met with legislative staffers about the regulation of marijuana infused edible products. OMM explained how THC levels are calculated, the safety rationale behind the maximum 10mg per serving size, and the maximum 50mg per package limit.

For Medical Marijuana Act regulations, proposed changes, previous changes, and contact information, visit the OMM website: http://dhss.delaware.gov/dph/hsp/medmarocreg.html.

Quality Control and Testing

Regarding testing, the law refers to potency and "contaminants," which state law does not define. DPH determined, as part of the regulatory process, that in addition to the obvious need to prevent mold, fungi, and insect infestations during the medical marijuana growing process, pesticides should also be prohibited. As a result, the use of pesticides in Delaware's growing process is prohibited. All companies that wish to open a Compassion Center in Delaware must articulate in their applications how they will grow the product without using pesticides and how they will prevent mold, fungi, and insect infestations. All product is tested prior to being sold.

To ensure that Delaware patients receive safe and consistent products that are free of pesticides and other contaminants, OMM contracts with the High Tide Lab Company of Camden, Delaware. High Tide Lab Company tests marijuana products sold in Delaware. The company, which holds an ISO 17025 accreditation, began testing marijuana products sold in Delaware in mid-January 2017. High Tide Lab Company utilizes gas and liquid chromatography to obtain cannabinoid profiles. Gas chromatography

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mass spectrometer is used to test for residual solvents and pesticides, including terpene analysis. Terpene analysis looks at the various terpenes found in cannabis products which play a role in the way tetrahydrocannabinol (THC) and cannabidiol (CBD) act on the endocannabinoid system when consumed for medicinal purposes. This impacts the effectiveness of the product in delivering medicinal results such as pain relief. The compassion centers are tested weekly, and the program receives the reports upon completion.

High Tide Lab purchased a replacement Inductively Coupled Plasma Mass Spectrometry (ICP-MS) instrument, which tests for heavy metals in products. Investing in the new ICP-MS was important with new growers beginning operations. The older unit was too expensive to operate daily.

Compliance Activities

The MMP revoked two patient cards for diversion of medical marijuana products in FY22. However, 133 applications were denied for various administrative reasons. Most of the applications were incomplete, lacked adequate documentation, or had unqualified signatures on the provider certification.

Participating Patients and Advocates Demographics

During FY22, the Delaware Department of Health and Social Services (DHSS), Division of Public Health's (DPH) Office of Medical Marijuana (OMM) issued 24,859 registration cards to participating program patients and advocates. The age of participating patients ranges from younger than 18 years old, with representation by an advocate, to over 80 years old. The highest percentage of the patient population is represented by those aged between 61-70 years old accounting for 24.3% of the total patients enrolled in the program (Figure 5). Fifty four percent of the patient population is composed of females (Figure 6). Of the participating patient population, New Castle County accounts for 51% of patients, Sussex County 31%, and Kent County 18% (Figure 7).

⁶ Using Gas Chromatography for Accurate Terpene Analysis in Cannabis (cannabissciencetech.com)

30.0% 25.0% 20.0% 15.0% 10.0% 5.0% 0.0% <18 18-25 26-30 31-40 41-50 51-60 61-70 71-80 >80 Percent 0.1% 3.8% 5.7% 15.9% 17.0% 21.7% 24.3% 9.6% 1.8% AGE

Figure 5. Percentage of Medical Marijuana Program Patient Population by Age, Delaware, Fiscal Year 2022

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database

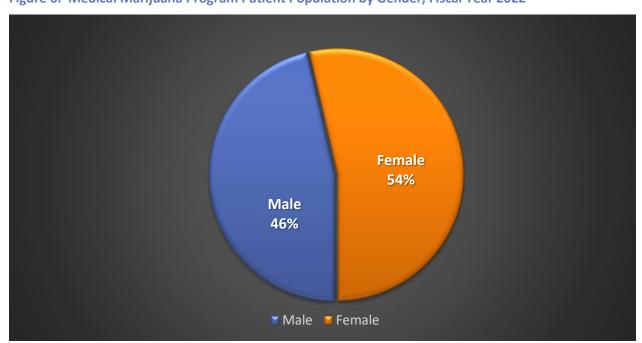


Figure 6. Medical Marijuana Program Patient Population by Gender, Fiscal Year 2022

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database

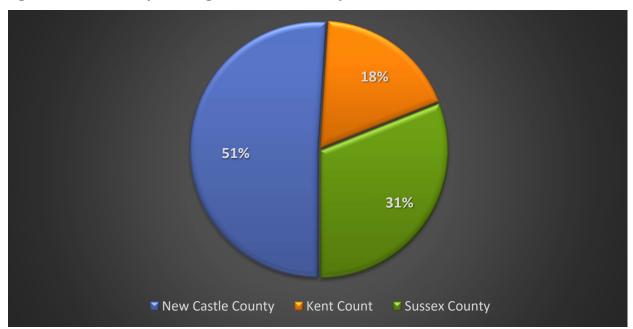


Figure 7. Medical Marijuana Program, Patient's County of Residence, Delaware, Fiscal Year 2022

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database.

Participating Physicians

Numerous Delaware medical professionals are participating in the program by completing and signing the medical professional's certification form for their patients. Of the participating medical professionals, 395 have offices in New Castle County, 135 have offices in Sussex County, and 80 have offices in Kent County (Figure 8).

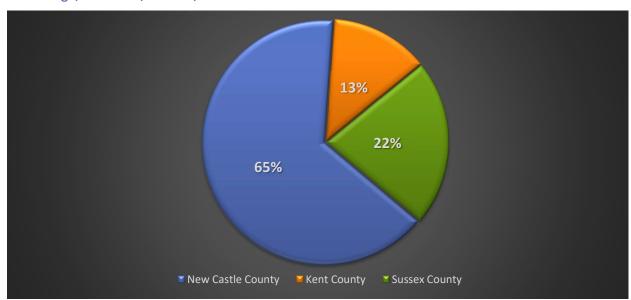


Figure 8: Medical Marijuana Program Participating Medical Professionals, by County, Count, and Percentage, Delaware, June 30, 2022

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database

Active Patient Debilitating Conditions

In 2017, The National Academies of Sciences, Engineering and Medicine issued a report called "The Health Effects of Cannabis and Cannabinoids." This report continues to show the therapeutic value of marijuana in treating a wide array of debilitating medical conditions. These include relief of chronic neuropathic or cancer pain; reduced use of opioids and analgesic enhancement for long-term pain management; less spasticity; and reduced nausea, vomiting, and weight loss associated with chronic debilitating conditions. Medical marijuana products may include cannabis compounds such as:

- THC, which activates pathways in the central nervous system that block pain signals to the brain, reduces nausea, and stimulates appetites in healthy and sick individuals.
- CBD, which reduces inflammation, pain, and anxiety without spasms, and treats some psychiatric conditions without lethargy, dysphoria, or feeling "high."
- THC-A is another cannabis product that comes in an oil or capsule. THC-A provides many of the same neurogenic and neuro-protectant benefits as CBD.

Patients interested in using medical marijuana to address conditions should discuss the issue with their medical professional.

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Section 2.0 of the State of Delaware Medical Marijuana Code lists the MMP qualifying debilitating medical conditions, under "Definitions of the regulations⁷." That list currently includes:

- The following medical conditions or treatment of these conditions:
 - o Cancer
 - Terminal illness
 - o Positive status for human immunodeficiency virus (HIV)
 - Acquired immune deficiency syndrome (AIDS)
 - Decompensated cirrhosis
 - o Amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease)
 - Post-traumatic stress disorder (PTSD)
 - Agitation of Alzheimer's disease
 - Autism with aggressive behavior
 - Chronic Debilitating Migraines
 - New daily persistent headache
 - o Glaucoma
- A chronic or debilitating disease or medical condition, or its treatment, which produces one or more of the following:
 - Cachexia or wasting syndrome
 - Severe, debilitating pain that has not responded to previously prescribed medication or surgical measures for more than three months or for which other treatment options produced serious side effects
 - o Intractable nausea
 - Seizures/Intractable Epilepsy
 - Severe and persistent muscle spasms, including but not limited to those characteristics of Multiple Sclerosis.

In FY21 and FY22, the three most common debilitating medical conditions among qualifying patients were: 1) severe, debilitating pain; 2) PTSD; and 3) muscle spasms. Figure 9 shows the number of active patients for each of the qualifying debilitating medical conditions.

⁷http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/ Division%20of%20Public%20Health/Health%20Systems%20Protection%20(HSP)/4470.shtml#1057590

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Figure 9. Number of Patients by Debilitating Conditions, Medical Marijuana Program, Delaware, Fiscal Years 2021 and 2022

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2022.

Financial Analysis

The Delaware Medical Marijuana Act requires revenue from the MMP to cover program expenses (Tables 3 and 4). Card revenue grew from \$684,878 in FY21 to \$819,550 in FY22, increasing \$134,672, the 20% year over year increase is a result of more patients entering the program. Compassion Center Fees dropped from \$415,000 in FY21 to \$240,000 in FY22, the 42% decrease of \$175,000 is caused by the two-year cycle of renewals. The Compassion Center Fee line will increase again in FY23 with the addition of new compassion centers opening.

Table 3. Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2021

FY21	Revenue	Expense
Registration Card Application and Replacement Fees Paid	\$684,878	
Compassion Center Fees	\$415,000	
Total Revenue	\$1,099,878	
Employee Expenses		\$381,222
Communications (postage, telecom, etc.)		\$19,828
Contract and Professional Services (legal notices, etc.)		\$62,046
Maintenance and Supplies (software maintenance, card		
supplies)		\$30,191
IT Equipment and Software		\$69,945
State Personnel Charges		\$1,570
Total Program Expenses		\$564,800

Source: State of Delaware, First State Financials System (FSF)

Table 4. Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2022

FY22	Revenue	Expense
Registration Card Application and Replacement Fees Paid	\$819,550	
Compassion Center Fees	\$240,000	
Total Revenue	\$1,059,550	
Employee Expenses		\$364,183
Communications (postage, telecom, etc.)		\$16,434
Contract and Professional Services (legal notices, etc.)		\$21,147
Maintenance and Supplies (software maintenance, card supplies)		\$21,338
IT Equipment and Software		\$87,238
State Personnel Charges		\$6,100
Total Program Expenses		\$516,440

Source: State of Delaware, First State Financials System (FSF)

V. Program Summary and Future

In FY22, as of July 2021, all members of Medical Marijuana Program returned to working exclusively for the OMM after three employees spent 15 months staffing the State Health Operations Center (SHOC) in response to the 2019 Coronavirus (COVID-19) pandemic. The three staff members deployed by OMM worked in the Call Center, SHOC Planning, Warehouse, and Vaccine Distribution.

OMM will initiate the MMP Stakeholder Group in the fall of 2022 following the sunset of the Medical Marijuana Act Oversight Committee during the last legislative session. The MMP stakeholder group will meet quarterly to discuss and address issues related to the MMP. The group will have representation from the Delaware registered patient and caregiver population, the medical and scientific communities, the Delaware-registered compassion centers, safety compliance facility, and the OMM.

In August 2021, a new medical marijuana vendor, "The Farm," opened a Kent County retail location in Felton. The centralized location has been very popular with patients in the center of the state. The Farm has an approved facility built for retail in New Castle, which will open in August 2022.

The OMM issued an initial grow permit for the new vendor "Valor Cannabis." The company initiated "pheno-hunting" and planted several strains to test the viability of each. Pheno-hunting is the science of striving for consistency by isolating seeds to pass the desired genetic traits of a plant to the next generation by isolating the dominant traits in their seeds. Valor Cannabis is operating in a temporary structure, as they have not received approval for the permanent structure.

The third vendor chosen in the 2020 request for applications (HSS 20-016) process is "Best Buds" which will be opening retail locations in Dover and Georgetown in the fall of 2022. The anticipated Best Buds grow facility in Wilmington was delayed by a zoning issue. Best Buds entered into several wholesale agreements with other medical marijuana vendors, which will allow it to open the retail center doors.

The MMP is committed to ongoing monitoring of patient needs and industry best practices to provide ongoing quality services. Post-COVID, OMM staff have directed their attention and efforts toward streamlining the application process by adding additional administrative staff. The program's focus remains centered on growth, improvement, and ensuring the quality of products supplied to the medical marijuana consumer base in the state of Delaware, as well as the accessibility to them.

⁸ Everything You Need To Know About Pheno Hunting | Flavor Fix