

Delaware Medical Marijuana Program Annual Report





Delaware Medical Marijuana Program Annual Report

October 2018

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Table of Contents

١.	Executive Summary	1
II.	Overview	
III.	Education and Outreach	Δ
	Inquiry Response	Δ
	Community Outreach	5
IV.	Legislative	6
	Request for Proposal and Contract	ε
	Quality Control and Testing	7
	Program Participation Analysis	7
	Compliance Activities	7
	Application Revenue	9
	Participating Physicians	11
	Active Patient Debilitating Conditions	12
	Financial Analysis	14
	Program Summary and Future	15

Table of Figures

gure 1: Medical Marijuana Program Cards Issued by Type, Delaware, Fiscal Year 2018	. 2
gure 2: Total Program Applications by Fiscal Year, Delaware, Fiscal Years 2013-2018	2
gure 3: Office of Medical Marijuana Program Revenue, Delaware, Fiscal Years 2017 and 2018	3
gure 4: Office of Medical Marijuana Registration Fees Collected, Delaware, Fiscal Years 2017 and 201	_
gure 5: Office of Medical Marijuana Website Hits, Delaware, Fiscal Years 2017 and 2018	.4
gure 6: Medical Marijuana Program Applications by Type and Month, Delaware, Fiscal Year 2018	.8
gure 7: Medical Marijuana Program Applications Received, Delaware, Fiscal Years 2017 and 2018	.8
gure 8: Number of Medical Marijuana Applications Approved by Amount of Fees Paid, Delaware, Fiscal Year 2018	9
gure 9: Medical Marijuana Program Patient Population by Age, Shown as Percentage and Number, Delaware, Fiscal Year 2018	10
gure 10: Medical Marijuana Program Patient Population by Gender, Delaware, Fiscal Year 2018	10
gure 11: Medical Marijuana Program Patient's County of Residence, Delaware, Fiscal Year 2018	11
gure 12: Medical Marijuana Program Participating Physicians, by County, Count, and Percentage, Delaware, June 30, 2018	11
gure 13: Debilitating Conditions, Medical Marijuana Program, Delaware, Fiscal Years 2017 and 2018:	13
gure 14: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2017	14
gure 15: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2018	15

Table of Contents Page ii

Delaware Medical Marijuana Program Annual Report

Program Year 6

July 1, 2017 - June 30, 2018 (State Fiscal Year 2018)

I. Executive Summary

This report documents the Delaware's Medical Marijuana Program's (MMP) growth, challenges, accomplishments, and activities during its sixth year, State Fiscal Year 2018 (FY18). This report is submitted as required by paragraph $\S4922A$ (b) of the Delaware Medical Marijuana Act (hereafter referred to as *the Act*). The Act, legislatively mandated by Chapter 49a of Delaware Code Title 16^2 , was approved and signed by Governor Jack Markell on May 13, 2011 and took effect on July 1, 2011.

The information in this report is designed to provide a historical account of the progression of the Medical Marijuana Program in Delaware 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.

Using the series of annual reports Delaware constituents and other states can follow the development of the marijuana industry in Delaware to understand the milestones and benchmarks of creating a new industry. This report and the preceding annual reports are memorialized on the State of Delaware Medical Marijuana Program website under the Medical Marijuana Oversight Committee tab located at https://dhss.delaware.gov/dhss/dph/hsp/medmaroc.html.

In June 2015, Delaware opened its first medical marijuana dispensary, the First State Compassion Center (FSCC) 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. 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, which is expected to open in New Castle County in November 2018. CCRI will have the growing and retail operation at the same Newark location.

¹ http://delcode.delaware.gov/title16/c049a/index.shtml

² http://delcode.delaware.gov/title16/c049a/index.shtml

Delaware Medical Marijuana Act Annual Report State Fiscal Year 2018

In Fiscal Year 2018 the total program applications increased by 85%. The patient population continued its steady increase of 104% and caregiver population increasing by 64%. The pediatric program increased by 90% while the new agent applications decreased year over year, however the program issued 179 renewals for agent cards. The program estimates by the end of FY 19 the monthly application processing rate will be 750 resulting in approximately 9,000 program participants.

II. Overview

During FY18, OMM issued 6,625 registration cards, 85 percent more than the 3,588 issued in FY17. FY18's cards are categorized as follows: 4,389 new patient cards (2017: 2,156); 1,648 patient renewal cards (2017: 1,181); 267 new caregiver cards (2017: 163); 72 caregiver renewal cards (2017: 42); 19 new pediatric cards (2017: 10); four pediatric renewal cards (201: 3); 30 new Minor Guardian cards (2017: 10); 17 new agent cards (2017: 74); and 179 renewal agent cards (2017: 35). (Figures 1 and 2.)

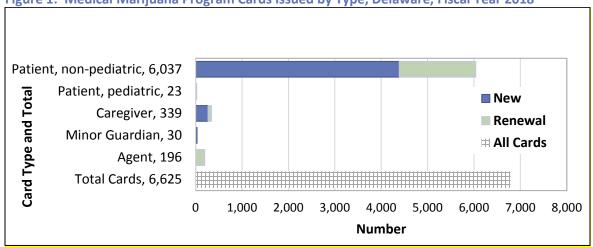
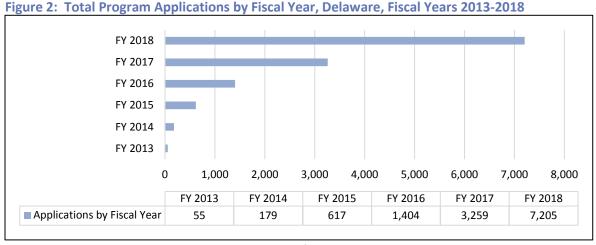


Figure 1: Medical Marijuana Program Cards Issued by Type, Delaware, Fiscal Year 2018

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

The Medical Marijuana Act requires revenue from the MMP was to cover the expenses of the program. MMP spending authority in the amount of \$480,100 was allocated for personnel and the costs of necessary equipment and supplies. (Figure 3.)

Figure 3: Office of Medical Marijuana Program Revenue, Delaware, Fiscal Years 2017 and 2018

State FY	Revenue	Expenses	Program Net
2017	\$418,985	\$375,257	\$43,728
2018	\$524,321	\$389,879	\$134,442

Source: Delaware's First State Financials (FSF) System, 2018.

The patient and caregiver registration fee remained at \$125 per fiscal year. OMM maintained the reduced-fee sliding scale policy outlined in DHSS's Policy Memorandum 37 (PM 37), updated with revised figures from the federal poverty guidelines. Sixty-seven percent of the applicants (3,181) paid the full \$125 fee. Nearly 29 percent (1,354) were approved for fee waivers and 178 were approved on the sliding scale, paying less than \$125. (Figure 4.)

Figure 4: Office of Medical Marijuana Registration Fees Collected, Delaware, Fiscal Years 2017 and 2018

State FY	Full Fee \$125		Less Than \$125	
2017	2,360	70%	1,013	30%
2018	3,181	67%	1,532	33%

Source: Delaware's First State Financials (FSF) System, 2018.

Education and Outreach III.

While providing medicinal marijuana to patients is the most visible aspect of the OMM, 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@state.de.us. In conjunction with DPH's Office of Health Risk Communication, OMM developed Frequently Asked Questions (FAQ) for patients, physicians, and law enforcement to 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. OMM's website includes FAQ brochures for patients, physicians, and law enforcement and are also available preprinted by request. In the past two fiscal years, the OMM website has received over 5,000 hits per month. (Figure 5.)

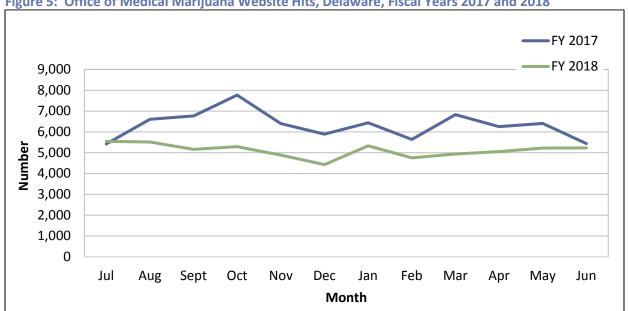


Figure 5: Office of Medical Marijuana Website Hits, Delaware, Fiscal Years 2017 and 2018

Source: Delaware Health and Social Services Internet site website statistics, Fiscal Years 2017 and 2018.

Community Outreach

The topic of medical marijuana is still controversial in many professional circles; some medical professionals and law enforcement have concerns about the safety or efficacy of medical marijuana. To address common misconceptions, Division of Public Health Director Dr. Karyl Rattay and MMP Administrator Paul Hyland conduct briefings and presentations to groups and medical practices. Medical Marijuana Compliance Manager Joseph Schlimer participates in briefings with law enforcement agencies and program compliance issues.

- In July 2017, Paul Hyland participated in the Americans for Safe Access (ASA) "End Pain, Not Lives" campaign kick-off meeting. There are several focus areas to increase medical provider awareness in Delaware. Pain management providers can being informed that appropriately documented chronic pain is a qualifying condition and medical marijuana may be an appropriate treatment as an alternative to opiates.
- In September 2017, Paul Hyland, Joseph Schlimer, and OMM Investigator Terrence Lyons attended the Driving Under the Influence Treatment Court Program Steering Committee meeting. Chief Justice Smalls requested the program present information relevant to the committee's work.
- In October 2017, Paul Hyland met with a local Psychiatrist, Dr. McIntosh on the subject of research. Dr. McIntosh stated he is interested in conducting research into the safe extraction of cannabinoids. Dr. McIntosh believes in putting greater emphasis on narrowing the inconsistencies in active ingredients; values will give patients more consistent products.
- In December 2017, Paul Hyland spoke at the Central Delaware Oncology Nursing Society Educational Conference about opiate use. Paul spoke for 90 minutes and answered questions before a large and very attentive audience of about 75 oncology nurses.
- In March 2018, Paul Hyland attended the Brain Injury Association conference and provided information about the MMP.
- In April 2018, Paul Hyland attended the Camden Rotary Club Dinner and provided information about the MMP.
- In June 2018, Paul Hyland and Joseph Schlimer conducted a briefing and program overview for Delaware Probation and Parole Officers in Kent County.

IV. Legislative

HB 374 with HA1 (An Act to amend Title 16 of the Delaware Code relating to the Medical Marijuana Act was introduced. The bill adds glaucoma and chronic debilitating migraines to the list of debilitating medical conditions which may qualify a person, upon certification by a physician, to be eligible for the use of medical marijuana.

HB 210 allows minors subject to debilitating medical conditions not specifically listed in Title 16 4906A(b) the same petition process to have their condition considered as that allowed for adults. For Medical Marijuana Act regulations, proposed changes, previous changes, and contact information, visit the OMM website: http://dhss.delaware.gov/dph/hsp/medmarocreg.html.

Request for Proposal and Contract

DHSS received numerous bid proposals in reference to RFP #HSS-16-010 Delaware Consolidated Cannabis Control System. The committee reviewed the proposals and selected a vendor. DHSS began contract negotiations.

The DEC3S System contract was awarded to Bio-Tech Medical Software, Inc (BioTrackTHC). OMM required a cloud-based solution to replace the current manual identification card application process used for medical marijuana patients. The system consolidated all of the current functions of the process into one platform, which automated the review and approval process. OMM now has the capability to accept applications online.

The DEC3S system also provides OMM with the ability to monitor facility inventory and sales data. It gathers and reports against real-time data with respect to compassion centers' plant and inventory locations, plant growth-phases, production phases, product conversion, laboratory quality assurance testing, transportation, destruction, and point-of-sale activities. The new system's tools and real-time data allow OMM to eliminate diversion and allow patients to make purchases at any location in Delaware.

Quality Control and Testing

By way of background, 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. The use of pesticides in the growing process is prohibited. Applicants are to articulate how they will grow the product without using pesticides and how they will prevent mold, fungi, and insect infestations.

High Tide Lab Company utilizes gas and liquid chromatography to obtain cannabinoid profiles to include a gas chromatography mass spectrometer to test for residual solvents and pesticides, and to perform terpene analysis.

High Tide Lab Company, which is accredited by ASA, is responsible for ensuring that Delaware patients receive safe and consistent products that are free of pesticides and other contaminants. It began testing marijuana products sold in Delaware in mid-January 2017.

Program Participation Analysis

OMM tracks program participation data as the number of registry card applications received for patients, caregivers, or agents. OMM received 7,200 registry card applications in FY18, 121 percent more than the 3,259 received in FY17. (Figures 6 and 7.)

Compliance Activities

DHSS revoked five patient cards for diversion in FY 18 and denied 518 applications for various administrative reasons. Most of the 518 applications were incomplete, lacked adequate documentation, or had unqualified signatures on the physician certification. The Act requires that the certifying physician be Delaware-licensed as either a medical doctor (MD) or a doctor of osteopathy (DO). DHSS does not accept signatures of physicians licensed in other states, resident doctors, and physician assistants.

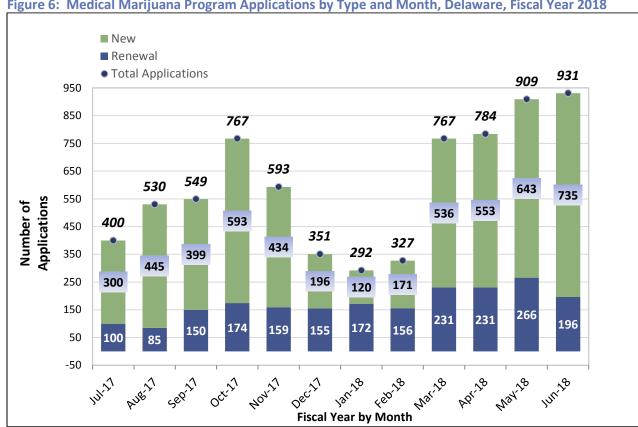
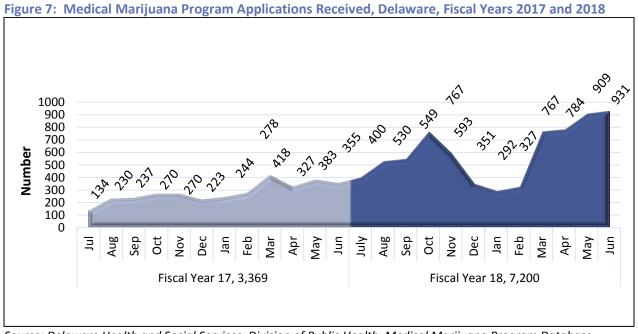


Figure 6: Medical Marijuana Program Applications by Type and Month, Delaware, Fiscal Year 2018

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

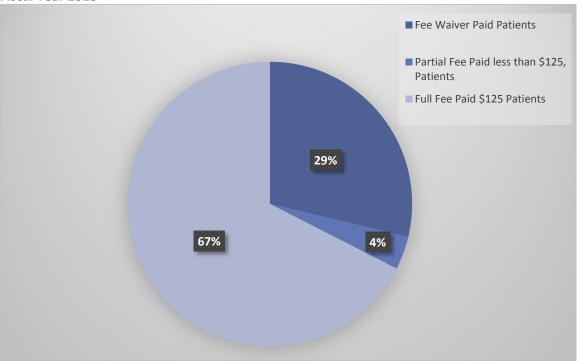


Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

Application Revenue

Sixty-seven percent of the applications received during FY18 included the full \$125 application fee (Figure 8). Twenty-nine percent included a request for a low-income fee waiver. OMM approved 4 percent for a partial payment based on the sliding income scale.

Figure 8: Number of Medical Marijuana Applications Approved by Amount of Fees Paid, Delaware, Fiscal Year 2018

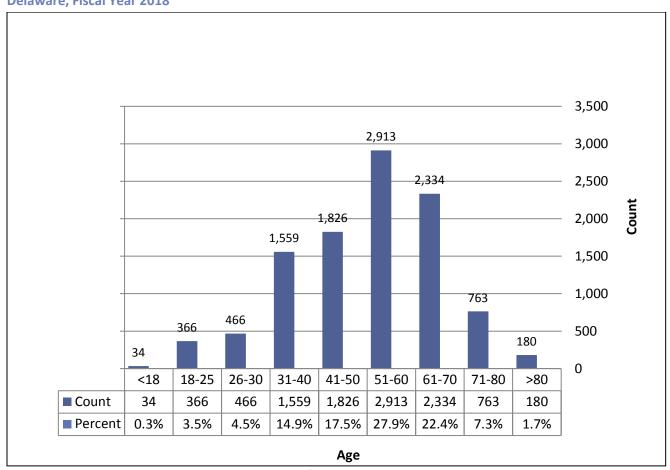


Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

Figures 9, 10, and 11 describe the medical marijuana patients:

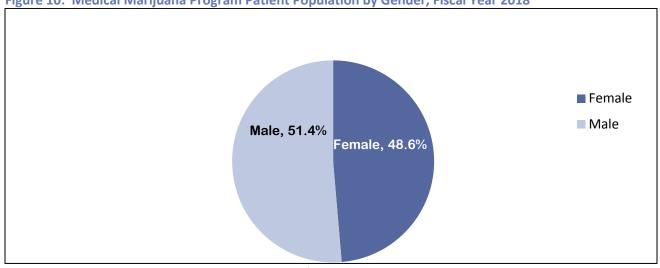
- Figure 9 depicts the age distribution.
- Figure 10 shows the gender breakdown of patients.
- Figure 11 shows the distribution of patients by county of residence.

Figure 9: Medical Marijuana Program Patient Population by Age, Shown as Percentage and Number, **Delaware, Fiscal Year 2018**



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

Figure 10: Medical Marijuana Program Patient Population by Gender, Fiscal Year 2018



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

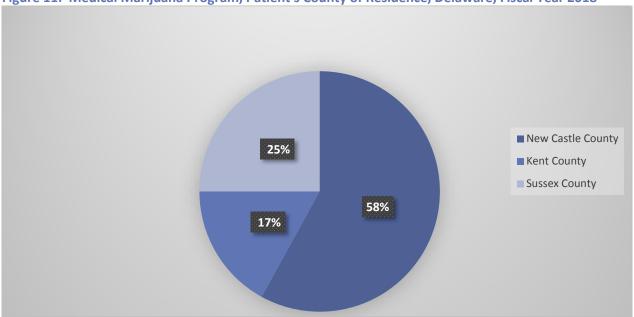


Figure 11: Medical Marijuana Program, Patient's County of Residence, Delaware, Fiscal Year 2018

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

Participating Physicians

As of June 30, 2018, 419 physicians are participating in the program by completing and signing the physician's certification form for their patients. Of the participating physicians, 269 have offices in New Castle County, 90 have offices in Sussex County, and 60 have offices in Kent County. (Figure 12.)

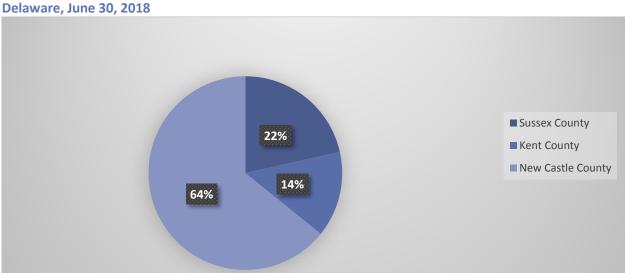


Figure 12: Medical Marijuana Program Participating Physicians, by County, Count, and Percentage, Delaware, June 30, 2018

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2017.

Active Patient Debilitating Conditions

According to published research, using 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. States that legalized marijuana for managing chronic pain may experience fewer deaths from prescription painkiller overdoses. Medical marijuana products may include cannabis compounds such as:

- Tetrahydrocannabinol (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.
- Cannabidiol (CBD), which reduces inflammation, pain, and anxiety without spasms, and treats some psychiatric conditions without lethargy, dysphoria, or feeling "high."
- THC acid, called 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 Cannabidiol.

Section 2.0 lists the MMP qualifying debilitating medical conditions, "Definitions of the regulations³." That list currently includes:

- The following medical conditions or treatment of these conditions:
 - o Cancer
 - o Terminal illness
 - Positive status for human immunodeficiency virus (HIV)
 - o Acquired immune deficiency syndrome (AIDS)
 - Decompensated cirrhosis
 - o Amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease)
 - o Post-traumatic stress disorder (PTSD)
 - o Agitation of Alzheimer's disease
 - Autism with aggressive behavior
- A chronic or debilitating disease medical condition or its treatment that produces one or more of the following:
 - o 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
 - o Seizures
 - Severe and persistent muscle spasms, including but not limited to, those characteristic of multiple sclerosis.

³ http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Division%20of%20Public%20Health/Health%20Systems%20Protection%20(HSP)/4470.shtml#1057590

Delaware Medical Marijuana Act Annual Report State Fiscal Year 2018

The three most common debilitating medical conditions among qualifying patients were: 1) severe, debilitating pain; 2) severe, persistent muscle spasms; and 3) cancer. The number of qualifying patients with PTSD noticeably increased due to the removal of the Psychiatrist's certification requirement. Figure 13 shows the number of active patients for each of the qualifying debilitating medical conditions.

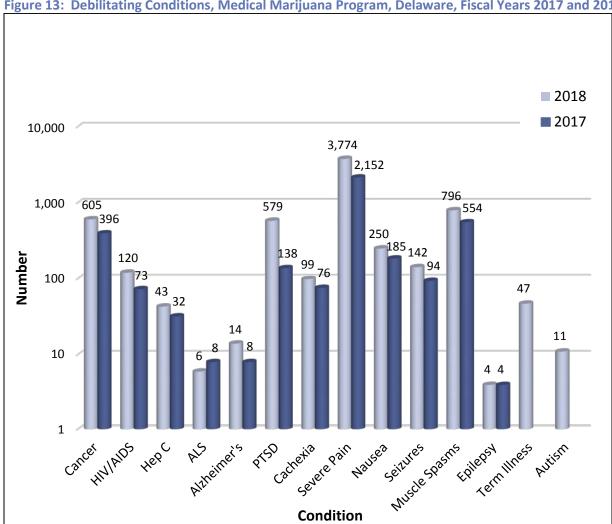


Figure 13: Debilitating Conditions, Medical Marijuana Program, Delaware, Fiscal Years 2017 and 2018

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2018.

Financial Analysis

Figure 14: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2017

	•		
FY17	Budget	Revenue	Expense
Registration Card Application and Replacement Fees Paid		\$298,985	
Compassion Center 2-year License Fee		\$120,000	
Total Revenue (71705)		\$418,985	
Appropriated Special Fund (61702) – up to revenue	\$418,985		
collected			
General Funds – Medical Marijuana (00313)	\$70,000		
Total Budget	\$488,985		
Employee Expenses			\$270,317
Communications (postage, telecom, etc.)			\$9,831
Contract and Professional Services (legal notices, etc.)			\$8,183
Maintenance and Supplies (software maintenance, card			\$17,550
supplies)			
IT Equipment and Software			\$34,919
Total Program Expenses			\$340,800

Source: Delaware First State Financials System, June 2017.

Figure 15: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2018

FY18	Budget	Revenue	Expense
Registration Card Application and Replacement Fees Paid		\$484,321	
Compassion Center Fees		\$40,000	
Total Revenue (71705)		\$524,321	
Appropriated Special Fund (61702) – up to revenue	\$480,100		
collected			
Total Budget	\$480,100		
Employee Expenses			\$305,604
Communications (postage, telecom, etc.)			\$8,383
Contract and Professional Services (legal notices, etc.)			\$20,037
Maintenance and Supplies (software maintenance, card			\$20,146
supplies)			
IT Equipment and Software			\$32,266
State Personnel Charges			\$3,443
Total Program Expenses			\$389,879

Source: Delaware First State Financials System, June 2018.

Program Summary and Future

Program growth continued in FY18 as the number of applications received and ID cards issued more than doubled FY17 numbers. This is consistent with the trend observed since FY13, when the program received 55 applications. There are no signs that this trend will slow during FY19.

In the next fiscal year, the program's focus is to facilitate the fourth compassion center opening in the fall of 2018 in Newark, and to enhance quality control initiatives. Delawareans in need of accessing medical marijuana dispensaries will benefit from having two compassion centers in New Castle County instead of one, as well as the compassion centers in each of Kent and Sussex counties. Since three different companies will be operating them, consumers may benefit from different products and economic competition.

OMM continues to make final changes to the new statewide medical marijuana-tracking program, known as the "Delaware Consolidated Cannabis Control System" (DEC3S). DEC3S allows medical marijuana patients to make purchases at any of the state-regulated compassion centers without worry of exceeding purchase limits. Another exciting benefit is the customer service enhancement that allows medical marijuana applicants to apply online for program identification cards and check their available limits.