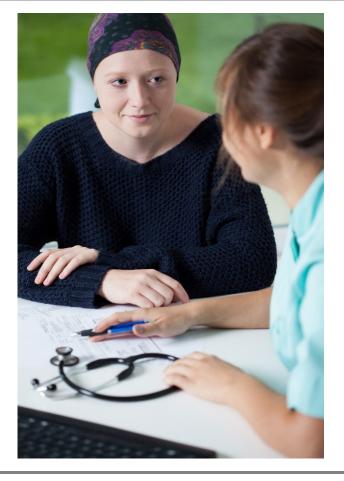


Delaware Medical Marijuana Program Annual Report



Fiscal Year



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Delaware Medical Marijuana Program Annual Report

Program Year 5

July 1, 2016 - June 30, 2017 (State Fiscal Year 2017)

I. Executive Summary

This report documents the Delaware's Medical Marijuana Program's (MMP) growth, challenges, accomplishments, and activities during its fifth year, State Fiscal Year 2017 (FY17). This report is submitted as required by paragraph §4922A (b)¹ of the Delaware Medical Marijuana Act (hereafter referred to as *the Act*) The Act, legislatively mandated by Chapter 49a of Delaware Code Title 16², was approved and signed by Governor Jack Markell on May 13, 2011 and took effect on July 1, 2011.

In February 2012, following federal guidance, the Governor suspended the establishment of three compassion centers, one in each county. However, the registry card program continued to be developed and began receiving applications on July 1, 2012.

After reviewing similar programs in other states, Governor Markell announced in an Aug. 15, 2013 letter to Delaware lawmakers that he directed Delaware Health and Social Services (DHSS) to issue a Request for Proposals (RFP) to establish, open, and operate a pilot compassion center in Delaware. The modified program addressed federal concerns explained in a memo from United States Deputy Attorney General James Cole³ that same month.

In June 2015, Delaware opened its first medical marijuana dispensary, the First State Compassion Center (FSCC), in Wilmington. In December 2015, Delaware Health and Social Services (DHSS) published a request for proposals (RFP) to establish, open, and operate two new compassion centers, one each in Kent and Sussex counties. Compassion Centers are the locations where patients obtain marijuana. DHSS awarded contracts in September 2016 to Columbia Care for Kent County and in October 2016 to the First State Compassion Center (FSCC) for Sussex County. FSCC in Sussex opened their Lewes location in May 2017. Columbia Care is expected to open in the spring of 2018.

After the RFP process was completed, the MMP on advisement from the MMP Oversight Committee, conducted research and analysis of the patient population and needs. This resulted in the state's issuing an RFP to open an additional compassion center in New Castle County. The committee advised MMP select the New Castle site based on the results of the original Kent and Sussex County RFP process. MMP selected Compassionate Care Research Institute (CCRI), which is expected to open in New Castle County in the spring of 2018. CCRI will be growing and doing retail at the same location.

In October 2016, MMP contracted with AgroLab Organics, Inc. to open the Medical Marijuana Safety and Compliance Facility. This facility opened its doors and conducted first testing of marijuana in January 2017, ensuring that Delaware's medical marijuana patients are obtaining safe and effective medical marijuana products.

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

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

http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf

II. Overview

During FY17, OMM issued 3,588 registration cards, 231 percent more than the 1,550 issued in FY16. FY17's cards are categorized as follows: 2,156 new patient cards (2016: 1,181); 1,105 patient renewal cards (2016: 226); 163 new caregiver cards (2016: 64); 42 caregiver renewal cards (2016: nine); 10 new pediatric cards (2016: seven); three pediatric renewal cards (2016: 0); 10 new Minor Guardian cards (2016: nine); 74 new agent cards (2016: 36); and 35 renewal agent cards (2016: 18). (Figures 1 and 2.)

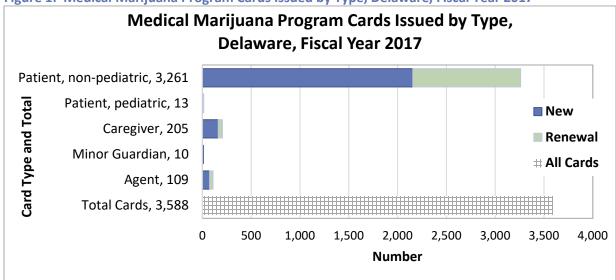


Figure 1: Medical Marijuana Program Cards Issued by Type, Delaware, Fiscal Year 2017

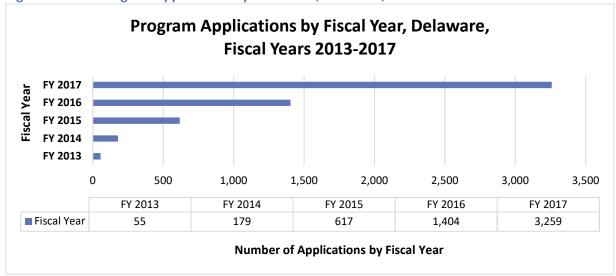


Figure 2: Total Program Applications by Fiscal Year, Delaware, Fiscal Years 2013-2017

Figure 3: Office of Medical Marijuana Program Revenue, Delaware, Fiscal Years 2016 and 2017

Office of Medical Ma	Office of Medical Marijuana Program Revenue, Delaware, Fiscal Years 2016 and 2017				
State FY	Revenue	Expenses	Program Net		
2016	\$218,381	\$116,794	\$101,587		
2017	\$418,985	\$375,257	\$43,728		

Source: Delaware's First State Financials (FSF) System, 2017.

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. Seventy percent of the applicants (2,360) paid the full \$125 fee. Nearly 30 percent (1,013) were approved for fee waivers and 34 were approved on the sliding scale, paying less than \$125. (Figure 4.)

Figure 4: Office of Medical Marijuana Registration Fees Collected, Delaware, Fiscal Years 2016 and 2017

Office of Medical Marijuana Registration Fees Collected, Delaware, Fiscal Years 2016 and 2017				
State FY	Full Fee \$125		Less Than \$125	
2016	1,143	74%	401	37%
2017	2,360	70%	1,013	30%

Source: Delaware's First State Financials (FSF) System, 2017.

III. Education and Outreach

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 Medical Marijuana Program 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 Communications (OHRC), 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 Frequently Asked Questions (FAQ) brochures for patients, physicians, and law enforcement. These are available preprinted by request and for download on the OMM program website.

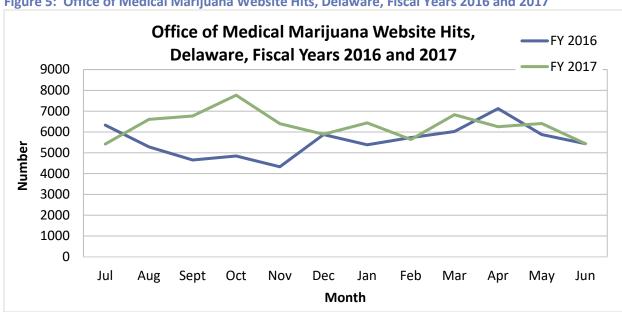


Figure 5: Office of Medical Marijuana Website Hits, Delaware, Fiscal Years 2016 and 2017

Source: Delaware Health and Social Services Internet site website statistics, Fiscal Years 2016 and 2017.

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 Medical Marijuana Program 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.

- On October 4, 2016, OMM conducted a presentation to the Delaware Nursing Home Residents Quality Assurance Commission (DNHRQAC) at their Fox Run facility.
- On November 1, 2016, the OMM Compliance Manager attended a town hall meeting sponsored by the Cannabis Bureau of Delaware and Delaware chapter of National Organization for the Reform of Marijuana Laws (NORML).
- On November 29, 2016, the OMM Program Administrator and Compliance Manager conducted a briefing and program overview for Delaware Probation and Parole officers in New Castle County.
- On January 18, 2017, OMM Program Administrator Paul Hyland spoke at the Medical Marijuana Town Hall at Churchman's Village in Newark, Delaware. The town hall focused on hospice and long term care patients. Other participants included Jason Silversteen, DO, neurologist with Christiana Care; Joel Allcock, FSCC director of cultivation; and Leonard Harrison, R.N. of the Christiana Visiting Nurse Association.
- On March 31, 2017, the OMM program administrator spoke to University of Delaware Master of Business Administration (MBA) graduate students about the medical marijuana industry in Delaware. The one-hour forum covered topics including regulation of pesticides, patient demographics, and program administration.
- On April 18, 2017, Division of Public Health Director Karyl Rattay, MD, MS spoke to a group of Advanced Practice Nurses at A.I. Dupont Hospital for Children about medical marijuana and the opioid epidemic.
- On April 18, 2017, the OMM program administrator and compliance manager conducted a
 presentation at the Americans for Safe Access (ASA) Annual Conference in Washington, D.C.
 Afterwards, they participated in a regulatory roundtable focusing on regulatory challenges and
 success within the medical marijuana industry.
- On May 16, 2017, the OMM hosted a meeting with Jan Roberts-Rudzinski, LCSW, MSS, MA from Partners in Health and Wellbeing to discuss how OMM could help with the study of the impact of the MMP on Delaware's mental health patients.
- Paul Hyland presented medical marijuana information at the American Case Management Association's Delmarva Chapter's annual convention in Ocean City, Maryland. The 90-minute talk covered all aspects of the program was well received by the 85 attendees.

IV. Legislative

The OMM updated regulations due to the passage of House Bill (HB) 400 ("Bob's Bill") and Senate Bill (SB) 181. HB 400, which expands upon SB90, became effective November 29, 2016. Known as "Rylie's Law," HB 400 classifies pain, anxiety, or depression related to a terminal illness as a qualified condition in the Delaware Medical Marijuana Act for patients younger than age 18, and they are restricted to using pediatric oil products. HB 400 also classifies terminal illness in adults as a qualifying condition.

SB 181, which became effective September 7, 2016, allows designated caregivers to possess and administer medical marijuana oil to minors on school buses and on the grounds of the preschool, primary, or secondary school in which the minor patient is enrolled. 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 and opened 11 bid proposals in April 2016. The seven-member committee reviewed the proposals the following month and selected vendors. DHSS notified the selected vendors and began contract negotiations.

Contracts were awarded to Columbia Care for Kent County and to the FSCC for Sussex County. FSCC in Sussex opened their Lewes location in May 2017. Columbia Care is expected to open in Kent County in the beginning of 2018. After the RFP process was completed, the MMP Oversight Committee advised the MMP to conduct research and analysis of the patient population and needs, resulting in the request to open an additional Compassion Center in New Castle County. DPH made the determination to open another New Castle County compassion center due to an increased demand; 68 percent of medical marijuana cardholders are in New Castle County.

The committee advised the MMP to make its New Castle selection based on the results of the original Kent and Sussex County RFP process. Per 4914A, DPH has the authority to issue three registration certificates (at least one in each county) to the highest scoring applicants who submitted proposals to the RFP. Pursuant to § 4914A(d), DPH is then authorized to issue three additional registration certificates to the highest scoring applicants who were not already awarded a registration certificate.

Compassionate Care Research Institute (CCRI) submitted bids as part of the Kent/Sussex compassion center RFP process and met the high scoring criteria in the law. DPH decided to use its statutory authority to select CCRI as the highest scoring non-selected applicant for the additional New Castle County location. It is expected to open in the beginning of 2018. CCRI will be growing and doing retail at the same location.

Under section § 4920A, the Department of Health and Social Services is prohibited from sharing the physical addresses of the compassion centers. As with other compassion centers, the department has encouraged CCRI to announce their location when they are ready and all potential security issues have been addressed.

Quality Control and Testing

The Act originally established a Registered Safety Compliance Facility to provide services such as testing marijuana produced for medical use for potency and contaminants. Responding to the requirements of third party testing, on June 30, 2016, OMM submitted and posted RFP# HHS 16-011 to the DHSS RFP website: http://bidcondocs.delaware.gov/HSS/HSS 16011Medmaritst rfp.pdf; the bids were reviewed in mid-September 2016.

The Medical Marijuana Safety and Compliance Facility contract was awarded to Agrolab Organics, Inc. on January 1, 2017. Agrolab is responsible for ensuring that Delaware patients receive safe and consistent products that are free of pesticides and other contaminants and began testing marijuana products in mid-January.

By way of background, regarding testing, the law refers to potency and "contaminants" which is not defined in the law. DPH determined, as part of the regulatory process, that in addition to the obvious need to prevent mold, fungus, and insect infestation during the growing process for medical marijuana, pesticides should also be prohibited. The RFP stated that pesticides are prohibited as part of the growing process, as well as requiring respondents to articulate how they will grow the product without using pesticides and prevent infestation from mold, fungus, and insects.

Program Participation Analysis

OMM tracks program participation data as the number of registry card applications received for patients, caregivers, or agents. OMM received 3,588 registry card applications in FY17, 231 percent more than the 1,550 received in FY16. (Figure 6.)

Compliance Activities

DHSS revoked one patient card for diversion in FY 16 and denied 66 applications for various administrative reasons. Most of the 66 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.

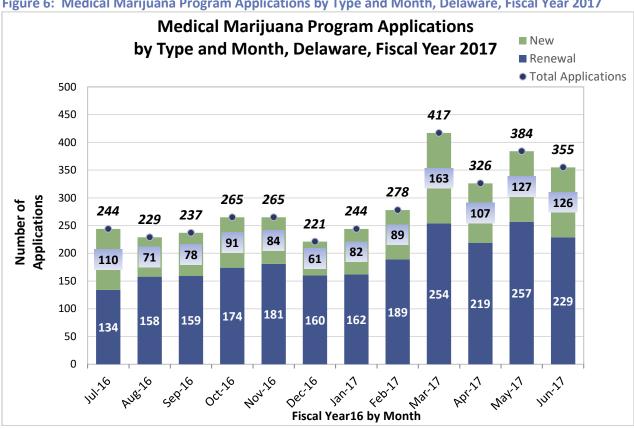
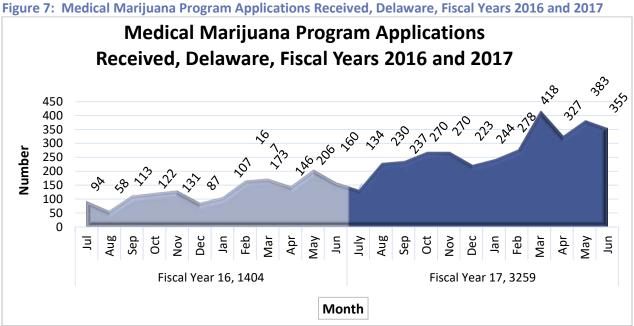


Figure 6: Medical Marijuana Program Applications by Type and Month, Delaware, Fiscal Year 2017



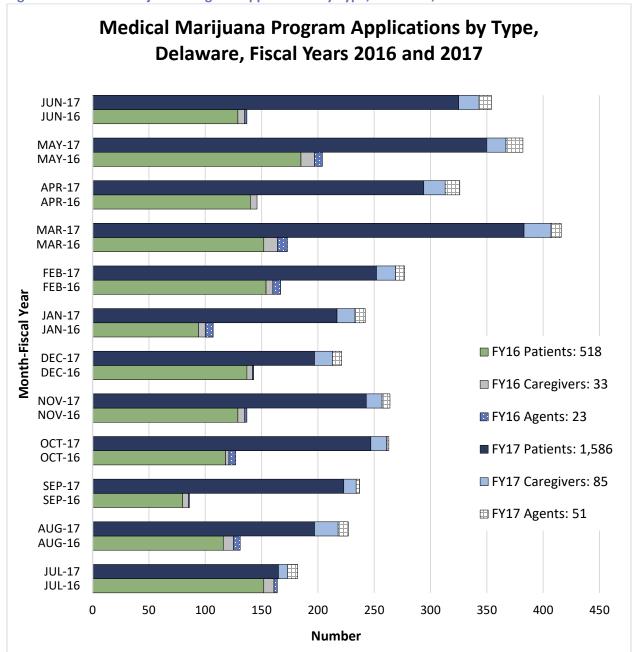
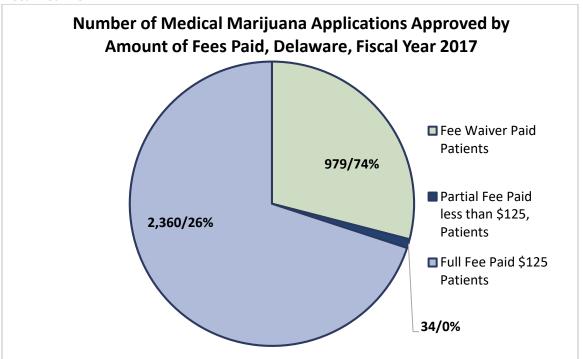


Figure 8: Medical Marijuana Program Applications by Type, Delaware, Fiscal Years 2016 and 2017

Application Revenue

Seventy-four percent of the applications received during FY17 included the full \$125 application fee (Figure 9). Twenty-six percent included a request for a low-income fee waiver. OMM approved 34 requests for a partial payment based on the sliding income scale. The other low-income requests qualified to have the fee waived (\$0 payment). In FY16, OMM processed 26 percent of the applications with fee waiver requests.

Figure 9: Number of Medical Marijuana Applications Approved by Amount of Fees Paid, Delaware, Fiscal Year 2017



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

Figures 10, 11, and 12 describe aspects of the medical marijuana patients:

- Figure 10 depicts the age distribution.
- Figure 11 shows the gender breakdown of the 3,373 patients.
- Figure 12 shows the distribution of patients by county of residence.

Figure 10: Medical Marijuana Program Patient Population by Age, Shown as Percentage and Number, Delaware, Fiscal Year 2017

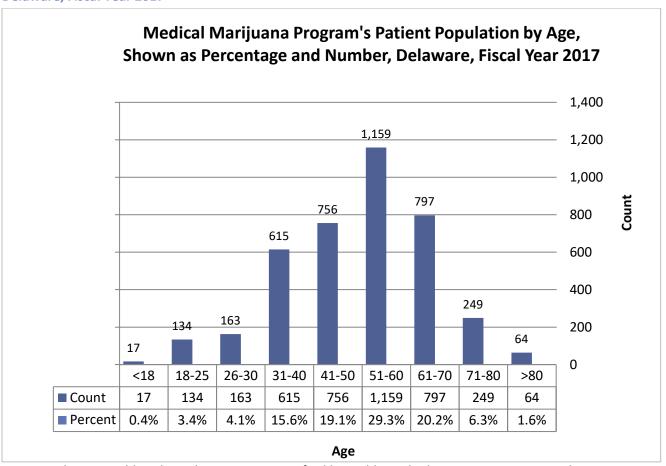
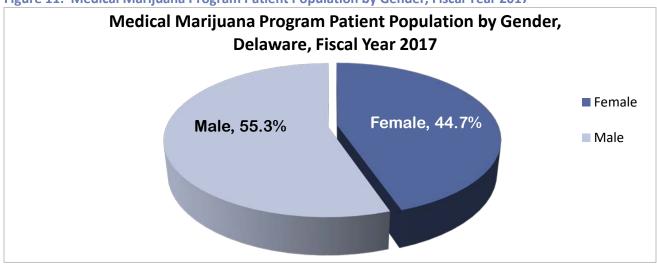


Figure 11: Medical Marijuana Program Patient Population by Gender, Fiscal Year 2017



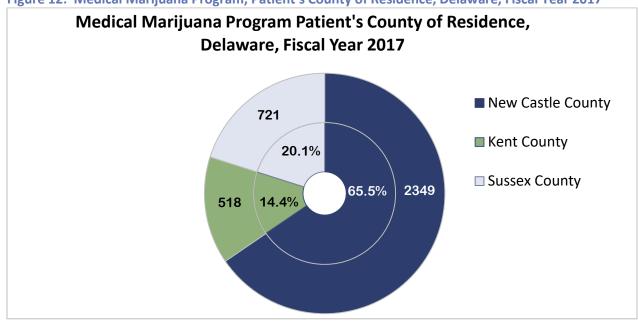


Figure 12: Medical Marijuana Program, Patient's County of Residence, Delaware, Fiscal Year 2017

Participating Physicians

As of June 30, 2017, 397 physicians are participating in the program by completing and signing the physician's certification form for their patients. Of the participating physicians, 274 have offices in New Castle County, 76 have offices in Sussex County, and 47 have offices in Kent County (Figure 13).

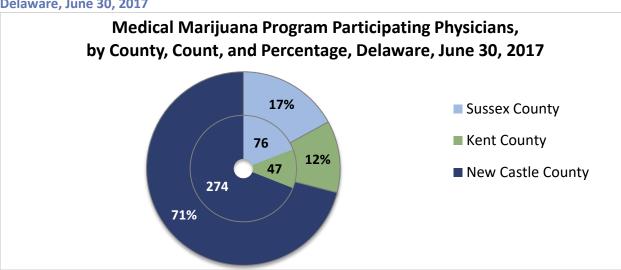


Figure 13: Medical Marijuana Program Participating Physicians, by County, Count, and Percentage, Delaware, June 30, 2017

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 have 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) 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) 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 regulations⁴." That list currently includes:

- The following medical conditions or treatment of these conditions:
 - o Cancer
 - Terminal illness
 - Positive status for human immunodeficiency virus (HIV)
 - Acquired immune deficiency syndrome (AIDS)
 - Decompensated cirrhosis
 - Amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease)
 - 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:
 - 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.

The three most common debilitating medical conditions among qualifying patients were: 1) severe, debilitating pain; 2) severe, persistent muscle spasms; and 3) cancer. Figure 14 shows the number of active patients for each of the qualifying debilitating medical conditions.

⁴http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Division%20of%20Public%20Health/Health%20Systems%20Protection%20(HSP)/4470.shtml#1057590

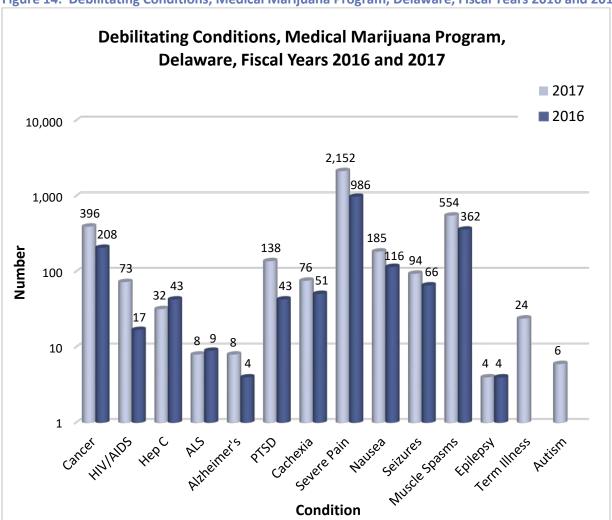


Figure 14: Debilitating Conditions, Medical Marijuana Program, Delaware, Fiscal Years 2016 and 2017

Financial Analysis

Figure 15: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2016

Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2016				
FY16	Budget	Revenue	Expense	
Registration Card Application and Replacement Fees Paid		\$143,670		
Compassion Center 2-year License Fee		\$55,000		
Total Revenue (71705)		\$198,670		
Appropriated Special Fund (61702) – up to revenue	\$198,670			
collected				
General Funds – Medical Marijuana (00313)	\$70,000			
Total Budget	\$268,670			
Employee Expenses (61702) and (00313)			\$113,996	
Communications (postage, telecom, etc.)			\$3,244	
Contract and Professional Services (legal notices, etc.)			\$2,010	
Maintenance and Supplies (software maintenance, card supplies)			\$11,327	
Appropriated Special Funds – MMP Revenue (61702) Expenses			\$116,794	
Total Program Expenses			\$131,327	

Source: Delaware First State Financials System, June 2017.

Figure 16: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2017

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 Bid Fees		\$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 (61702 & 00313)			\$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.

Program Summary and Future

Program growth continued in FY17 as the number of applications received and ID cards issued more than doubled FY16 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 FY18.

In the next fiscal year, the program's focus is to facilitate the compassion center openings in the spring of 2018 and to enhance quality control initiatives. Delawareans in need of accessing medical marijuana dispensaries will benefit from the compassionate care centers opening in Kent and New Castle counties. Since three different companies will be operating, consumers may benefit from different products and economic competition.

The MMP is finalizing a new statewide medical marijuana tracking program, known as the "Delaware Consolidated Cannabis Control System" (DEC3S). DEC3S will allow medical marijuana patients to make purchases at any of the state-regulated compassion centers without worry of exceeding purchase limits. This new program is expected to be in service by early 2018. Another initiative currently under development is a customer service enhancement that allows medical marijuana applicants to apply online for program identification cards.