

Delaware Medical Marijuana Program Annual Report





DELAWARE HEALTH AND SOCIAL SERVICES Division of Public Health Medical Marijuana Program

Published January 2017

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Delaware Medical Marijuana Program Annual Report

Program Year 4

July 1, 2015 - June 30, 2016 (State Fiscal Year 2016)

I. Introduction

This report is a snapshot of Delaware's Medical Marijuana Program (MMP) in its fourth year. In State Fiscal Year 2016 (FY16), Delaware's only medical marijuana dispensary, the First State Compassion Center (FSCC), had been open one full year. Delaware Health and Social Services (DHSS) initiated the Request for Proposals (RFP) to open two additional compassion centers. The selected bidders will open centers in Kent County and Sussex County in State Fiscal Year 17 (FY17).

II. Overview

The Delaware Medical Marijuana Act (hereafter referred to as *the Act*), Chapter 49a of Delaware Code Title 16¹, 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 DHSS to issue an 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 Cole² that same month.

The purpose of this report is to document the development activities of the MMP during its fourth year by highlighting the growth, challenges, and accomplishments of FY16. This report is submitted as required by paragraph 94922A (b)³ of the Act.

In December 2015, DHSS published an RFP to open two new compassion centers in Delaware, one each in Kent and Sussex counties. The Office of Medical Marijuana (OMM) hosted a mandatory pre-bid meeting in February 2016, attended by 44 potential bidders representing 29 entities. OMM received more than 100 questions from the potential bidders both prior to and during the meeting. OMM received 11 bids from seven different bidders. All four Sussex County bidders also bid for Kent County. The diverse, DHSS-selected bid review committee evaluated the proposals in June 2016 and identified a presumptive vendor for each county, based on the RFP grading rubric. DHSS entered the contract negotiation process with the selected vendors in August 2016. Contracts were awarded to Columbia Care for Kent County and to the First State Compassion Center (FSCC) for Sussex County. FSCC in Sussex is expected to open in early 2017 and Columbia Care is expected to open in the fall of 2017.

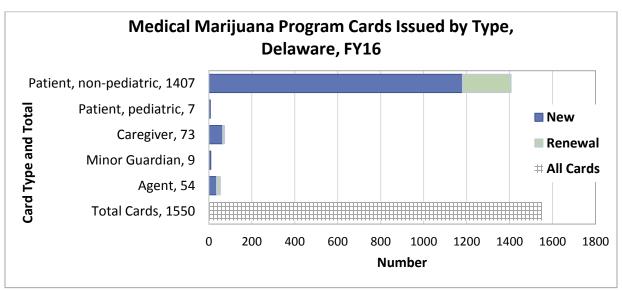
¹ <u>http://delcode.delaware.gov/title16/c049a/index.shtml</u>

² http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf

³ <u>http://delcode.delaware.gov/title16/c049a/index.shtml</u>

In FY16, OMM experienced explosive patient growth of 480 percent over FY15, registering new patients and renewing existing cardholders. Given the varying nature of the annual card expiration dates and the fluidity of the application process, the number of cards issued does not correspond directly to the number of active applicants.

During FY15, OMM issued 357 registration cards: 320 patients, 19 caregivers, and 18 agents. In comparison, during FY16, OMM issued 1,550 registration cards: 1,181 new patient cards, 226 patient renewal cards, 64 new caregiver cards, nine caregiver renewal cards, seven new pediatric cards, nine new Minor Guardian cards, 36 new agent cards, and 18 renewal agent cards. (See Figure 1 for cards issued and Figure 2 for monthly growth.)





Source: Division of Public Health, Medical Marijuana Program Database, July 2016.

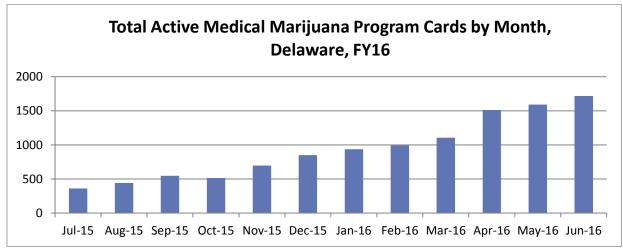


Figure 2: Total Active Medical Marijuana Program Cards by Month, Delaware, FY16

Source: Division of Public Health, Medical Marijuana Program Database, July 2016

Program revenue increased significantly in FY16 due to \$55,000 received from RFP application fees. The 11 vendors submitting RFPs each paid a \$5,000 application fee. See Figure 3.

Office of Medical Marijuana Program Revenue, Delaware, FY15 and FY16					
State FY	Revenue	Expenses	Program Net		
2015	\$92,895	\$94,699	\$-1,804		
2016	\$218,381	\$116,794	\$101,587		

			-	
Figure 3:	Office of Medical	Marijuana Progra	m Revenue, De	elaware, FY15 and FY16

Source: Delaware's First State Financials (FSF) System, 2016

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 guideline. Seventy-four percent of the applicants (1,143) paid the full \$125 fee. Of the remaining 401 cards, 397 (26 percent) were approved for fee waiver and four (less than 1 percent) were approved on the sliding scale, paying less than \$125. (See Figure 4.)

Figure 4.	Office of Medical Marijuana	Registration Fees	Collected	Delaware EV15 and EV16
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Office of Medical Marijuana Registration Fees Collected, Delaware, FY15 and FY16					
State FY	Full Fee	\$125	Less Than \$125		
2015	357	68%	162	32%	
2016	1143	74%	401	26%	

Source: Delaware's First State Financials (FSF) System, 2016

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 to 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. 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 a handy e-mail address: <u>MedicalMarijuanaDPH@state.de.us</u>. 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. The FAQ brochures are now available preprinted by request and for download on the OMM program website.

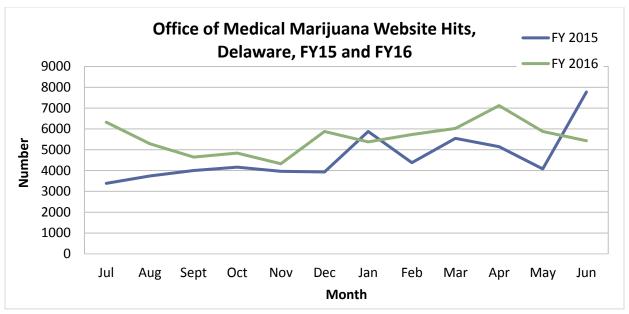


Figure 5: Office of Medical Marijuana Website Hits, Delaware, FY15 and FY16

Source: Delaware Health and Social Services Internet site website statistics, Fiscal Years 2015 and 2016

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 the Director of Public Health, Dr. Karyl Rattay and the Medical Marijuana Program Administrator, Paul Hyland conduct briefings and presentations to a variety of groups and medical practices. The Medical Marijuana Compliance Manager, Joseph Schlimer, participates in briefings dealing with Law Enforcement agencies or program compliance issues.

- On July 27, 2015, Paul Hyland and Joseph Schlimer conducted a briefing for members of the Delaware State Police Drug Diversion Unit at Troop 6 in Wilmington. The presentation focused on the Medical Marijuana Program, its history, and its mission. The presentation included a tour of the First State Compassion Center (FSCC) where a question and answer session was conducted with FSCC President Mark Lally and FSCC Vice President Joel Allcock.
- OMM collaborated with the Medical Society of Delaware (MSD) for a "Hot Topic" discussion on September 30, 2015, featuring DPH Director Karyl T. Rattay, MD, MS; Medical Marijuana Program Administrator Paul Hyland; and Joel Allcock, Vice President of First State Compassion Center. The 90-minute presentation at the MSD touched on an array of topics. The discussion was very productive for the program, as 30 physicians attended directly and via three video remote locations. The MSD granted three CMEs for the evening session.
- At Bayhealth's request, on Oct. 27, 2015, Paul Hyland and Joel Allcock gave a presentation to the professional staff at Kent General Hospital and broadcast to Milford Hospital.

- On December 11, 2015, OMM hosted a full access FSCC tour for representatives from the Delaware State Police Drug Unit from Troop 2. The tour followed the entire process from cloning the plant to trimming, curing, packaging, and delivering medical grade marijuana to patients. The tour gave the State Police a much clearer understanding of the Medical Marijuana Program.
- In response to a request from the Manager of Oncology Nursing and Research at Beebe Healthcare's Tunnell Cancer Center, Dr. Rattay provided a brief presentation for Beebe providers about the use of medical marijuana on April 12, 2016. Her presentation focused on evidence-based medical studies showing the benefits of medical marijuana use in cancer patients, the legalities of the medical marijuana, documentation, and ingestion options.
- On March 16, 2016, Paul Hyland spoke at the film premier of "Rolling Papers" at Cinema Art Theater in Dartmouth Plaza, Lewes, Delaware.
- The Office of Medical Marijuana met with representatives from FSCC and the University of Delaware's Center for Drug and Health Studies (UD-CDHS) in late March 2016. The UD-CDHS has collaborated with OMM in the past. The Center wanted to help with data collection in product strain and efficacy to build the research pool. The program received a proposal from the UD to further increase the collaboration between OMM, CDHS and the First State Compassion Center; the proposal aims to gather quantitative and qualitative data from program participants and use the results of the study to improve the program.

IV. Compliance Activities

On August 27, 2015, OMM hosted two public hearings on regulations: the first was to add Autism with Aggressive Behaviors to the list of qualifying conditions, and the second was for the proposed MMP regulation edits submitted in the August issue of the *Delaware Register of Regulations*.

At the first hearing, the petitioner, the mother of an adult son who suffered from Autism prior to his death, spoke about her son. A friend who helped her with the petition accompanied her. Additionally, a second mother of an adult child with the same condition attended in support of the petition, and she asked how OMM would implement the program in out-of-home settings, such as group homes and hospice care. Until the Federal government changes the restrictions that allow facilities that receive Medicare to participate in medical marijuana programs, facilities will have to sacrifice their federal funding. DPH understands no facility feels financially able to do so at this time. A rule change is required on the federal level.

Two advocates attended the second hearing. One did not offer remarks, while the other, a pending patient, did. His remarks involved topics such as reciprocation with other states, which OMM has previously addressed. The State of Delaware is not able to pursue reciprocity with surrounding states due to the wide variations in state laws. A patient could make a completely legal purchase in Delaware and cross the border to New Jersey and be in violation of New Jersey law, due to caps on THC delta 9 or purchase limits. Additionally, and most important, moving medical marijuana from one state to another state is a federal crime.

Staffing

Effective February 4, 2016, OMM reorganized under the DPH Director's Office and included responsibilities for the Clean Indoor Air Act. The office's first floor location in Suite 130 of the Jesse Cooper Building provides very convenient access for patients. The street address is 417 Federal Street, Dover, DE 19901.

OMM receives between six and 10 calls hourly for status updates, requests for applications, and directions. OMM established a call management system that provides automated answers to the most common issues, while also providing callers the option to speak directly to the staff. The system became operational on March 30, 2016, and immediately the staff noticed a significant boost in productivity.

OMM re-worked the patient and physician database to eliminate some bugs that have plagued the spreadsheet since its last upgrade in February 2015. A comprehensive Statewide IT solution purchase is planned in FY17. When the program's former Management Analyst II resigned, Joseph Schlimer accepted the position in August 2016.

Regulations

The OMM submitted Emergency Regulations to eliminate the 150-plant limitation and other conditions related to the passage of SB-90, which became effective on August 1, 2015. The codified regulations are included in Section 4470 of Title 16⁴ of Delaware's Administrative Code. For Medical Marijuana Act regulations, proposed changes, previous changes, and contact information, visit the OMM website: <u>http://dhss.delaware.gov/dph/hsp/medmarocreg.html</u>

The routine Regulation Update process began in March 2016, when OMM received a petition to add terminal illness as a qualifying condition under the State regulations. In accordance with the regulations, the petition was found to have merit. On April 7, 2016, the petition was posted on the OMM website: <u>http://dhss.delaware.gov/dph/hsp/medmarhome.html</u>; and a public hearing was held on June 7, 2016 for final determination.

Request for Proposal and Contract

In November 2015, OMM submitted RFP# HSS 16 003 for the Registration and Operation of a Medical Marijuana Compassion Center in Kent and Sussex Counties. On December 2, 2015, DHSS posted the RFP on the State's procurement portal at <u>http://mymarketplace.delaware.gov/</u>. DHSS collected questions from potential vendors regarding the RFP until mid-January 2016, per the RFP published schedule.

On February 1, 2016, OMM hosted a mandatory pre-bid meeting for the RFP to open two new compassion centers in Delaware. Forty-four potential bidders attended, representing 29 entities, to ask questions about the RFP. OMM received more than 100 questions from the potential bidders both prior to, and during, the meeting. Attendees included representatives from various program stakeholder groups, including advocacy groups, patients, and potential compassion center owners. OMM joined questions from the meeting with questions posed prior to the meeting, and published responses on the state procurement portal in April.

⁴<u>http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/</u> Division%20of%20Public%20Health/Health%20Systems%20Protection%20%28HSP%29/4470.shtml

Also in March 2016, DHSS selected members for a Request for Proposals (RFP) review committee to provide diversity in thought, experience, and perspective, given the unique nature of the medical marijuana industry. The committee included representation from the Delaware Public Health Laboratory (DPHL) and the Delaware Departments of Agriculture and Safety and Homeland Security. It also embodied stakeholders such as the DHSS Medical Director and a DHSS Information Resource Management (IRM) representative.

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. Due to the level of detail involved with the contract, DHSS moved the contract start date from August 2016 to October 2016.

Program Development

OMM posted the Medical Marijuana Act Oversight Committee agenda and by-laws on the Delaware State Public Calendar website <u>https://publicmeetings.delaware.gov/</u> in preparation for the initial meeting on October 27, 2015 at 5:30 p.m. in the Jesse Cooper Building's third floor conference room. The Committee passed the by-laws and elected Senator Margaret Rose Henry as the Committee Chair and Drewry Fennel as the Vice Chair. Thirty-five constituents attended the public meeting and presented public comments for over 30 minutes.

OMM hosted the second committee meeting at the DHSS Chapel on February 29, 2016 at 5:30 p.m. The meeting hosted nearly 50 citizens included 45 minutes for public comment. Meeting agendas are listed on the State of Delaware's public calendar and the minutes are posted to the public calendar site: https://publicmeetings.delaware.gov/Meeting/50525.

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, and training cardholders and prospective compassion center agents. The training would include safe and efficient cultivation, harvesting, packaging, labeling, and distribution of marijuana; best security practices; inventory accountability procedures, and scientific and medical research findings related to medical marijuana.

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:

<u>http://bidcondocs.delaware.gov/HSS/HSS_16011Medmaritst_rfp.pdf</u>; the bids were reviewed in mid-September 2016.

Program Participation Analysis

OMM tracks program participation data as the number of applications received. The application figure counts the number of individuals who have applied for a registry card: patient, caregiver or agents. OMM received 1,550 registry card applications in FY16, 276 percent more than the 561 received in FY15. The data in Figure 6 includes all the applications received from patients, caregivers, and compassion center agents.

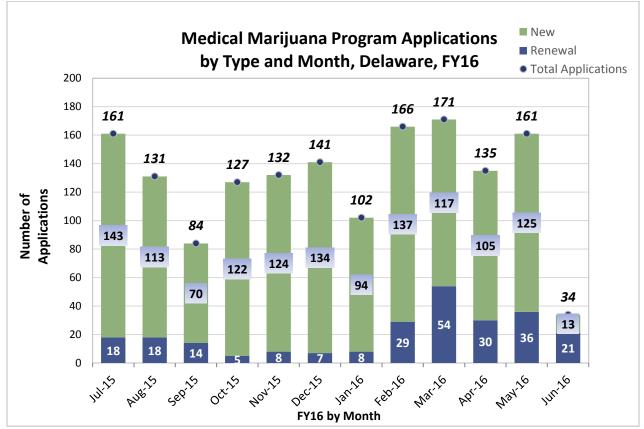
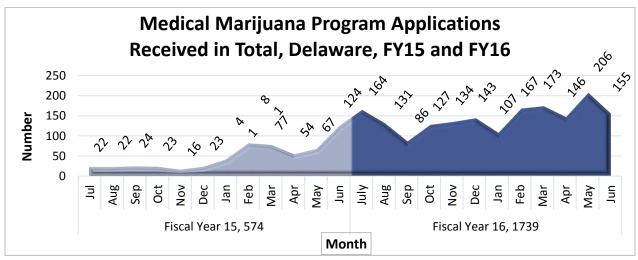


Figure 6: Medical Marijuana Program Applications, by Type and Month, Delaware, FY16

Source: Division of Public Health, Medical Marijuana Program Database, July 2016

Figure 7 shows the application volume comparison between FY15 and FY16. It also notes corresponding events related to the opening of the compassion center in June 2015.





Source: Division of Public Health, Medical Marijuana Program Database, July 2016.

Figure 8 shows the same data displayed a different way. In this chart, the stacked bars representing FY15 and FY16 are itemized to show application types that make up each of the data points. Each color in each bar is a different type of application received: patient, caregiver, and agent. Each set represents a month of the state fiscal year.

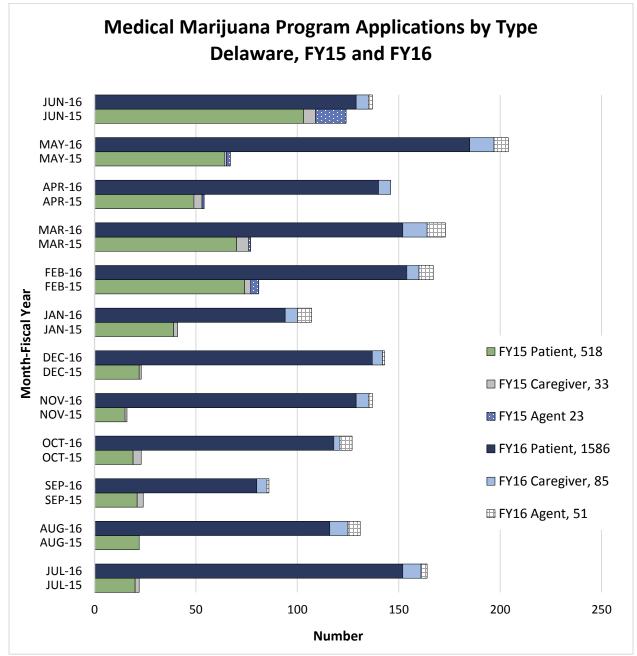


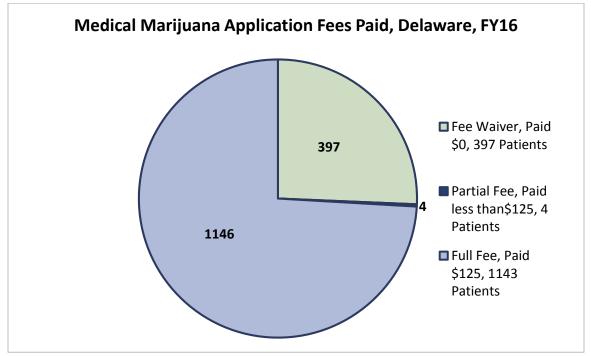
Figure 8: Medical Marijuana Program Applications by Type, Delaware, FY15 and FY16

Source: Division of Public Health, Medical Marijuana Program Database, July 2016

Application Revenue

As shown in Figure 9, 74 percent of the applications received during FY16 included the full \$125 application fee. Twenty-six percent included a request for a low-income fee waiver. OMM approved four 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 FY15, OMM processed 24 percent or 134 of the applications with fee waiver requests. The number of applications OMM processes with no fee, even if denied, affects the projected revenue generated from the application fees.





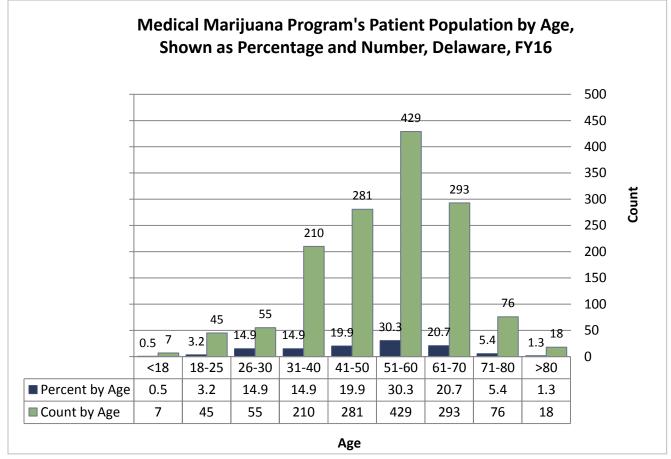
Source: Division of Public Health, Medical Marijuana Program Database, July 2016

DHSS denied 30 applications for various administrative reasons. Fourteen 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). Signatures of physicians licensed in other states, resident doctors, and physician's assistants are not accepted.

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

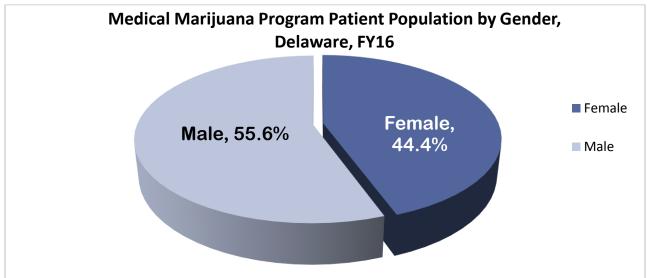
- Figure 10 depicts the age distribution
- Figure 11 shows the gender breakdown of the 1,550 patients
- Figure 12 shows county of residence

Figure 10: Medical Marijuana Program Patient Population by Age, Shown as Percentage and Number, Delaware, FY16



Source: Division of Public Health, Medical Marijuana Program Database, July 2016.





Source: Division of Public Health, Medical Marijuana Program Database, July 2016.

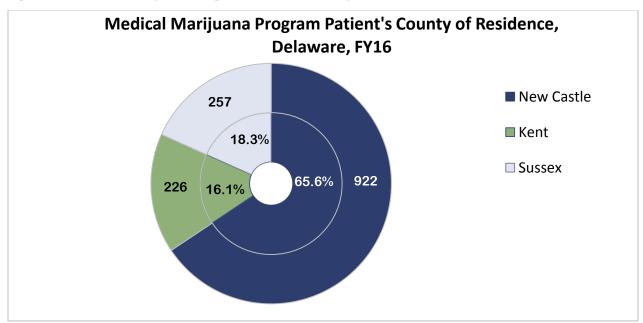


Figure 12: Medical Marijuana Program, Patient's County of Residence, Delaware, FY16

Source: Division of Public Health, Medical Marijuana Program Database, July 2016.

Participating Physicians

As of June 30, 2016, 299 physicians are participating in the program by completing and signing the physician's certification form for their patients. Fourteen of these doctors certified more than one of their patients for the MMP card program. Of the participating physicians, 211 have offices in New Castle County, 52 have offices in Sussex County, and 36 have offices in Kent County (See Figure 13).

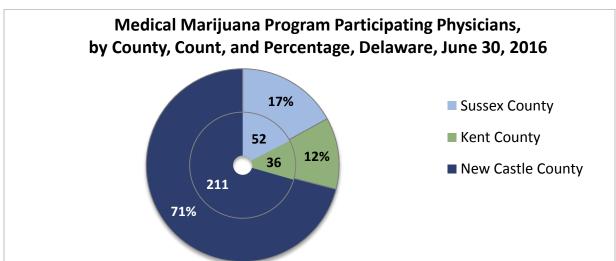


Figure 13: Medical Marijuana Program Participating Physicians, by County, Count, and Percentage, Delaware, June 30, 2016

Source: Division of Public Health, Medical Marijuana Program Database, July 2016.

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 regulations⁵." That list currently includes:

- The following medical conditions or treatment of these conditions:
 - o Cancer
 - 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); and
 - agitation of Alzheimer's disease; or
 - o Autism
- 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; or
 - 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. The number of patients with muscle spasms doubled in FY16, compared to FY15; many of these patients have multiple sclerosis. The number of patients with cancer increased four-fold during the same period.

⁵<u>http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/</u> Division%20of%20Public%20Health/Health%20Systems%20Protection%20(HSP)/4470.shtml#1057590

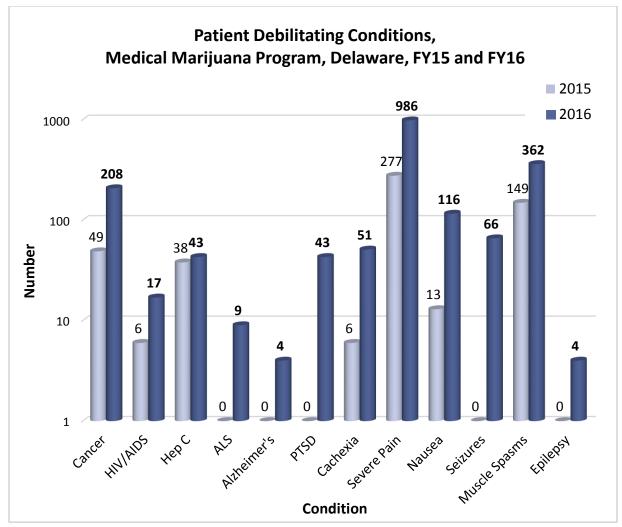


Figure 14: Patient Debilitating Conditions, Medical Marijuana Program, Delaware, FY2015 and 2016

Source: Division of Public Health, Medical Marijuana Program Database, July 2016

Financial Analysis

Section §4923A (5)⁶ of the Act stipulates the MMP be a financially self-supported program. In FY16, the program received \$70,000 in General Funds in appropriation 00313 to offset the projected revenue shortfall in the program. OMM's relocation to the first floor of the Cooper Building resulted in expenses in furniture and equipment purchases; however, the new location is much more accessible to patients.

⁶ <u>http://delcode.delaware.gov/title16/c049a/index.shtml#4923A</u>

Figure 15: Medical Marijuana Program Revenue and Expenses by year, Delaware, FY15

Medical Marijuana Program Revenue and Expenses by Year, FY15					
FY15	Budget	Revenue	Expense		
Registration Card Application and Replacement Fees Paid		\$52,900			
Compassion Center 2-year License Fee		\$40,000			
Total Revenue (71705)		\$92,900			
Appropriated Special Fund (61702) – up to revenue collected	\$92,900				
General Funds – Medical Marijuana (00313)	\$70,000				
Total Budget	\$162,900				
Employee Expenses			\$104,700		
Communications (postage, telecom, etc.)			\$1,500		
Contract and Professional Services (legal notices, etc.)			\$1,200		
Maintenance and Supplies (software maintenance, card supplies)			\$700		
Revenue Refund			\$100		
Appropriated Special Funds – MMP Revenue (61702) Expenses			\$94,500		
Total Program Expenses			\$108,200		

Source: Delaware First State Financials System, June 2015.

Figure 16: Medical Marijuana Program Revenue and Expenses by year, Delaware, FY16

Medical Marijuana Program Revenue and Expenses by Year, FY16				
FY16	Budget	Revenue	Expense	
Registration Card Application and Replacement Fees Paid		\$143,670		
Compassion Center Bid Fees		\$55,000		
Total Revenue (71705)		\$198,670		
Appropriated Special Fund (61702) – up to revenue collected	\$198,670			
General Funds – Medical Marijuana (00313)	\$70,000			
Total Budget	\$268,670			
Employee Expenses (61702 & 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	
Revenue Refund			\$750	
Appropriated Special Funds – MMP Revenue (61702) Expenses			\$116,794	
Total Program Expenses			\$131,327	

Source: Delaware First State Financials System, June 2016.

Program Revenue

MMP's FY16 revenue was \$198,670, from fees for card application, lost cards, and RFP bids.

Program Summary and Future

In FY16, the Medical Marijuana Program went through some significant changes, including a 480 percent growth in patient population and preparing to open new compassion centers in Kent and Sussex County in FY17. Contracts were awarded to Columbia Care for Kent County and to the First State Compassion Center (FSCC) for Sussex County. FSCC in Sussex is expected to open in early 2017 and Columbia Care is expected to open in the fall of 2017.

Additionally, with the opening of the new compassion centers, the program will introduce the statewide medical marijuana-tracking program, known as "Delaware Consolidated Cannabis Control System" (DEC3S). DEC3S will allow patients to make purchases at any of the State regulated compassion centers without worrying about exceeding purchase limits, while helping the program regulators increase inventory accountability.

All indications point to continued growth of the program through FY17 with the projected patient population growing to over 3,000 and the caregiver population exceeding 175. With the opening of a full growing operation in Kent County and a retail-only operation in Sussex County, the number of medical marijuana industry employees, also known as Agent cardholders, should reach 150 in FY17.

Finally, in FY17, the program will establish the Testing and Compliance Center featuring third party testing of all products. This new feature will ensure that Delaware patients receive safe and consistent products that are free of pesticides and other contaminates.