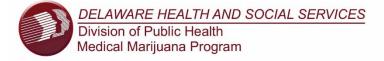


Delaware Medical Marijuana Program Annual Report





FISCAL YEAR 2019



Delaware Medical Marijuana Program Annual Report

Fiscal Year 2019

Questions or comments concerning this report and summary can be directed to the Delaware Department of Health and Social Services, Division of Public Health, Office of Medical Marijuana at 302-744-4749 or by mail or fax to this address:

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

October 2019



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Delaware Medical Marijuana Program Annual Report

Program Year 7

July 1, 2018 - June 30, 2019 (State Fiscal Year 2019)

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. Marijuana is a psychoactive drug derived from the Cannabis 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. 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, antibiotic-resistant infections, epilepsy, and other neurological disorders. THC acid (THC-A) provides many of the same neurogenic and neuro-protectant benefits as Cannabidiol when used in a capsule or oil.

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^{1} , 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 seventh year, State Fiscal Year 2019 (FY19). This report is submitted as required by paragraph §4922A (b)² of the Delaware Medical Marijuana Act.

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.

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

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

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- 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 of creating a new industry. This report and the preceding annual reports posted to the MMP website, are 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 called Compassion Centers. There are four Compassion Centers in Delaware; one company operates two of them. DPH contracts with the companies to both grow and sell medical marijuana in the state. A company must operate both a grow facility and a sales facility; they are not permitted to only operate one or the other.

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. Further information and locations of Delaware's Compassion Centers can be found at https://dhss.delaware.gov/dph/hsp/medmarcc.html

II. Overview

Only individuals who are issued a medical marijuana card via the MMP may purchase medical marijuana at a Compassion Center. During FY19, OMM issued 12,045 registration cards, 82 percent more than the 6,625 issued in State Fiscal Year 2018 (FY18). As depicted in Figures 1 and 2, FY19's cards are categorized as follows:

- 7,881 new patient cards (2018: 4,389)
- 3,292 patient renewal cards (2018: 1,648)
- 339 new caregiver cards (2018: 267)
- 125 caregiver renewal cards (2018: 72)
- 28 new pediatric cards (2018: 19)
- 12 pediatric renewal cards (2018: 4)
- 47 new Minor Guardian cards (2018: 30)
- 15 renewal Minor Guardian cards (2018:15)
- 220 new agent cards (2018: 17); and
- 86 renewal agent cards (2018: 179).

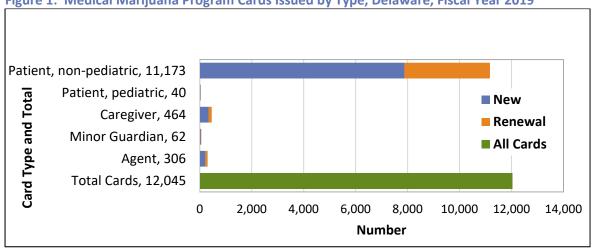


Figure 1: Medical Marijuana Program Cards Issued by Type, Delaware, Fiscal Year 2019

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

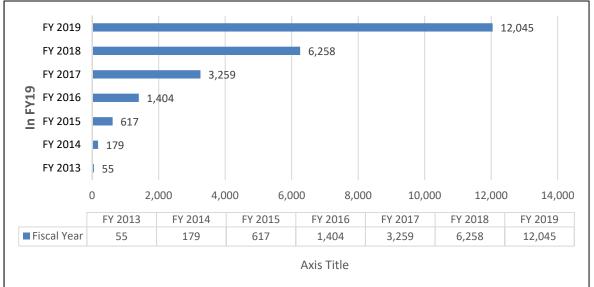


Figure 2: Total Medical Marijuana Program Applications by Fiscal Year, Delaware, Fiscal Years 2013-2019

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

The Delaware Medical Marijuana Act requires revenue from the MMP to cover program expenses. In FY 19 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 2018 and 2019

State Fiscal Year		Revenue	Expenses	Program Net	
	2018	\$524,321	\$389,879	\$134,442	
	2019	\$859,516	\$400,614	\$458,902	

Source: Delaware's First State Financials (FSF) System, 2019.

In FY19, the patient and caregiver application fee remained at \$125 per fiscal year. OMM maintained the reduced-fee sliding scale policy outlined in the DHSS Policy Memorandum 37, updated with revised figures from the federal poverty guidelines. Sixty-nine percent of the applicants (5,376) paid the full \$125 fee. Nearly 28 percent (2,213) were approved for fee waivers and 222 were approved on the sliding scale, paying less than \$125. (Figure 4.)

Application Revenue

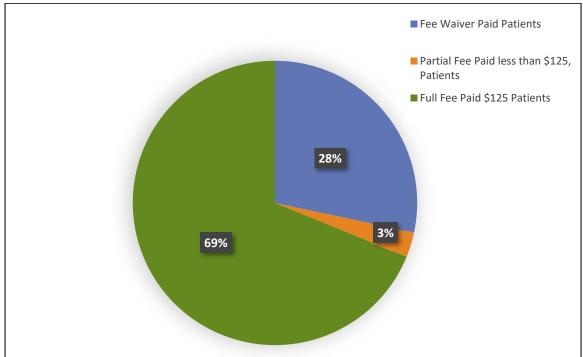
Figure 4: Number and Percentages of Medical Marijuana Fees Collected, Delaware, Fiscal Years 2018 and 2019

State Fiscal Year	Full Fee \$125		Less Than \$125		
2018	3,181	67%	1,532	33%	
2019	5,376	69%	2,435	31%	

Source: Delaware's First State Financials (FSF) System, 2019.

Sixty-nine percent of the applications received during FY19 included the full \$125 application fee (Figure 5). Twenty-eight percent included a request for a low-income fee waiver. OMM approved 3 percent for a partial payment based on the sliding income scale.

Figure 5: Number of Medical Marijuana Applications Approved by Amount of Fees Paid, Delaware, Fiscal Year 2019



Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

Education and Outreach III.

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@state.de.us. In conjunction with DPH's Office of Health and 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. Preprinted copies are available by request. In the past two fiscal years, the OMM website received over 5,000 hits per month. (Figure 6.)

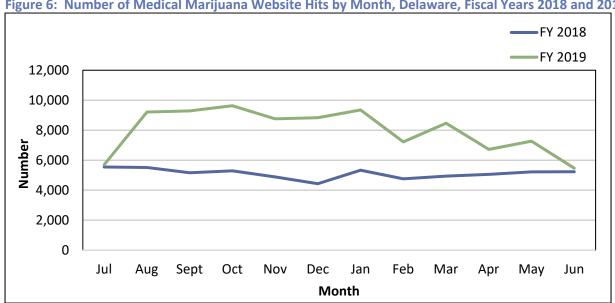


Figure 6: Number of Medical Marijuana Website Hits by Month, Delaware, Fiscal Years 2018 and 2019

Source: Delaware Department of Health and Social Services Internet site Internal Resource Management statistics, Fiscal Years 2018 and 2019.

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, DPH Director Dr. Karyl Rattay and MMP Administrator Paul Hyland conduct briefings and presentations to groups and medical practices.

- In July 2018, OMM and Columbia Care Compassion Center hosted a tour of their Milford facility for the Delaware Alcohol and Tobacco Enforcement and local dignitaries.
- In October 2018, OMM hosted a tour of the state's medical marijuana facilities for the Department of Insurance (DOI). The DOI was working on a multi-state task force dealing with liability issues related to the marijuana industry.
- In November 2018, OMM attended and conducted a briefing at the Delmarva Emergency Nurses
 Association Conference. The briefing focused on the Medical Marijuana Act and program
 specifics.
- In January 2019, DPH Director Dr. Karyl Rattay and MMP Administrator Paul Hyland made a
 presentation about the MMP to the Sickle Cell Anemia group at Nemours/AI DuPont Hospital for
 Children.
- In February 2019, DPH Director Dr. Karyl Rattay and MMP Administrator Paul Hyland conducted a presentation about the MMP at the Special Populations Group meeting held at Christiana Care Health System.
- In March 2019 for state legislators, OMM conducted a pre-Grand Opening tour of CCRI's Fresh Cannabis Company's Compassion Center in Newark.
- In March 2019, MMP Administrator Paul Hyland presented on Delaware's MMP at the Canna East Conference in New York.
- In April 2019, MMP Administrator Paul Hyland gave a presentation about the Medical Marijuana Program to Beebe Home Health Care workers.

IV. Legislative

House Bill 141 with House Amendment A1 (An Act to amend Title 16 of the Delaware Code relating to the Medical Marijuana Act) was passed. The bill adds "New daily persistent headache" and "Chronic debilitating migraines" to the list of chronic or debilitating medical conditions for which a child under 18 may qualify as a patient to receive marijuana oil. This bill also adds "New daily persistent headache" to the list of chronic debilitating medical conditions that qualifies an adult to be eligible for the use of medical marijuana.

Senate Substitute 1 for Senate Bill 24 amended by Senate Amendment 1 (An Act to amend Title 16 of the Delaware Code relating to the Medical Marijuana Act) was passed in July 2019. The bill allows a patient to apply for a compassionate use medical marijuana card when a doctor recommends medical marijuana to a patient who does not have a qualifying debilitating medical condition. 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

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. 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 Harrington, Delaware. High Tide Lab Company tests marijuana products sold in Delaware. The company, which is accredited by Americans for Safe Access (ASA), 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 mass spectrometer is used to test for residual solvents and pesticides, to include terpene analysis. The centers are tested weekly and the program receives the reports upon completion.

Compliance Activities

The MMP did not revoke any patient cards for diversion of medical marijuana products in FY19. However, 750 applications were denied for various administrative reasons. Most of the 750 applications were incomplete, lacked adequate documentation, or had unqualified signatures on the physician certification. The Delaware Medical Marijuana Act requires that the certifying physician be Delaware-licensed as either a medical doctor (MD) or a doctor of osteopathy (DO). MMP does not accept signatures of physicians licensed in other states, resident doctors, and physician assistants.

30.0% 25.0% 20.0% 15.0% 10.0% 5.0% 0.0% 18-25 26-30 31-40 41-50 51-60 61-70 <18 71-80 >80 Percent 0.3% 2.8% 4.6% 13.4% 16.8% 25.8% 23.9% 10.0% 2.3% Age

Figure 7: Medical Marijuana Program Patient Population by Age, Shown as Percentage Delaware, Fiscal Year 2019

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

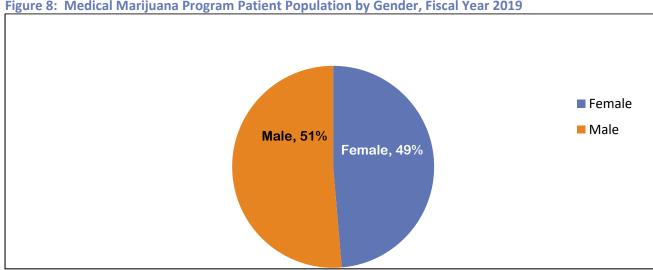
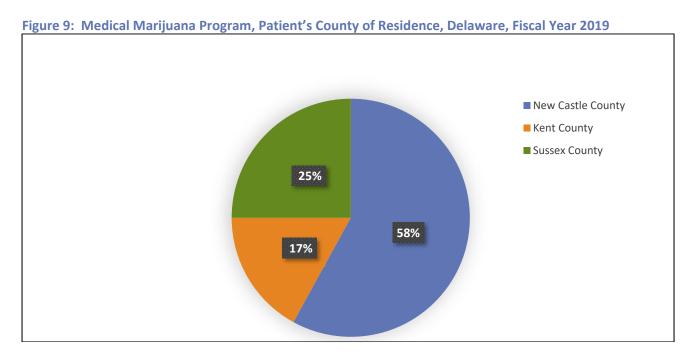


Figure 8: Medical Marijuana Program Patient Population by Gender, Fiscal Year 2019

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

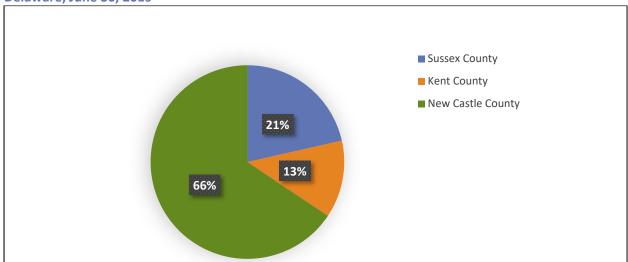


Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

Participating Physicians

As of June 30, 2019, 471 physicians are participating in the program by completing and signing the physician's certification form for their patients. Of the participating physicians, 309 have offices in New Castle County, 101 have offices in Sussex County, and 61 have offices in Kent County. (Figure 12.)

Figure 10: Medical Marijuana Program Participating Physicians, by County, Count, and Percentage, Delaware, June 30, 2019



Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

Active Patient Debilitating Conditions

Studies published since the 1999 Institute of Medicine report have continued 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; 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. 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.

Section 2.0 of the State of Delaware Medical Marijuana Code lists the MMP qualifying debilitating medical conditions, under "Definitions of the regulations³." 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
 - Amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease)
 - o Post-traumatic stress disorder (PTSD)
 - o Agitation of Alzheimer's disease
 - o Autism with aggressive behavior
 - o Chronic Debilitating Migraines
 - o New daily persistent headache
 - o Glaucoma
- A chronic or debilitating disease or 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
 - Seizures/Intractable Epilepsy
 - Severe and persistent muscle spasms, including but not limited to, those characteristic of multiple sclerosis.

In FY 18 and 19, the three most common debilitating medical conditions among qualifying patients were: 1) severe, debilitating pain; 2) PTSD; and 3) muscle spasms. Figure 11 shows the number of active patients for each of the qualifying debilitating medical conditions. There is no data for "Persistent Headache" because it was just added to the conditions list.

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

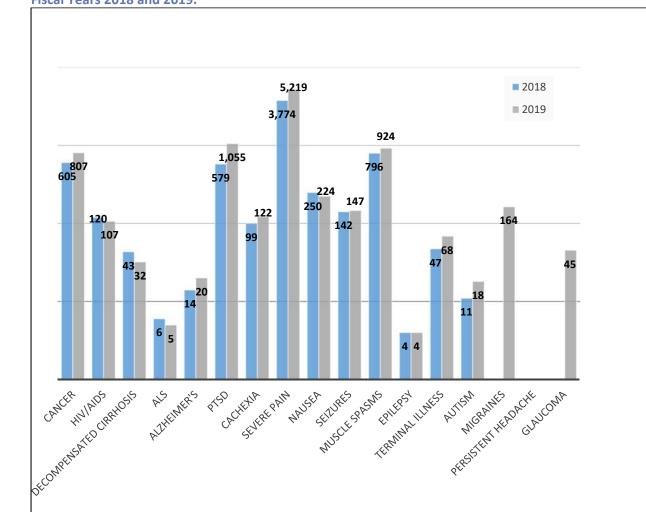


Figure 11: Number of Patients, by Debilitating Conditions, Medical Marijuana Program, Delaware, Fiscal Years 2018 and 2019.

Source: Delaware Department of Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2019.

Financial Analysis

Figure 12: 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		\$524,321	
Appropriated Special Fund (61702) — up to revenue collected	\$480,100		
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 supplies)			\$20,146
IT Equipment and Software			\$32,266
State Personnel Charges			\$3,443
Total Program Expenses			\$389,879

Source: Delaware First State Financials System, June 2019.

Figure 13: Medical Marijuana Program Revenue and Expenses, Delaware, Fiscal Year 2019

FY19	Budget	Revenue	Expense
Registration Card Application and Replacement Fees Paid		\$679,506	
Compassion Center Fees		\$180,000	
Total Revenue		\$859,516	
Appropriated Special Fund (61702) – up to revenue	\$480,100		
collected			
Total Budget	\$480,100		
Employee Expenses			\$319,145
Communications (postage, telecom, etc.)			\$21,975
Contract and Professional Services (legal notices, etc.)			\$46,791
Maintenance and Supplies (software maintenance, card			\$7,860
supplies)			
IT Equipment and Software			\$3,741
State Personnel Charges			\$1,102
Total Program Expenses			\$400,614

Source: Delaware First State Financials System, June 2019.

Program Summary and Future

DPH's MMP growth continued in FY19 with the addition of "Chronic Debilitating Migraines" and "New Daily Persistent Headache" to the list of debilitating conditions. The OMM expects continued program growth in FY20 due to the addition of the Compassionate Use Card, codified through Senate Bill 24, and signed into law October 2019. The Compassionate Use Card will allow physicians to certify a patient for a condition that is not currently listed as a debilitating condition under Title 16, Chapter 49a of the Delaware Code (4902A)(3).

The MMP is facilitating the opening of the state's fifth compassion center in Wilmington, scheduled for the fall of 2019. Delawareans in need of accessing medical marijuana dispensaries will then benefit from having three compassion centers in New Castle County instead of two, as well as the compassion centers in each of Kent and Sussex counties. Currently OMM is evaluating patient data to determine the necessity of a proposal to open other Compassion Centers in Kent and Sussex counties.

The Medical Marijuana Oversight Committee requested that OMM restructure the Medical Marijuana application fees for FY20 to be more in line with surrounding states medical marijuana programs. Now applicants will only pay \$50.00 instead of the current \$125.00 application fee for both new and renewal registrations. Applicants with income at or below 138 percent of the Federal Poverty Level will receive their registration card for \$25.00.

OMM continues to enhance the medical marijuana-tracking program known as the "Delaware Consolidated Cannabis Control System" (DEC3S). DEC3S allows medical marijuana applicants to apply online for program identification cards and check their available limits with a new mobile Identification feature. The mobile identification feature allows cardholders to access an electronic copy of their identification card from their mobile phone.

The MMP is committed to ongoing monitoring of patient needs and industry best practices in order to provide ongoing quality services in the state of Delaware.