



Delaware Medical Marijuana Program Annual Report



2014



DELAWARE HEALTH AND SOCIAL SERVICES
Division of Public Health
Health Systems Protection

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Delaware Medical Marijuana Program Annual Report

Program Year 2

July 1, 2013 - June 30, 2014 (State Fiscal Year 2014)

I. Introduction

This report is a snapshot of Delaware's Medical Marijuana Program (MMP) in its second year. The focus in State Fiscal Year 2014 (FY14) was to establish a pilot compassion center using the state's procurement process to identify the most qualified vendor. The Delaware Department of Health and Social Services (DHSS) started contract negotiations with the successful vendor, First State Compassion Center (FSCC), by the end of FY14, and signed a contract with them early in State Fiscal Year 2015 (FY15). This second annual report explains program participation levels, education and outreach achievements, interagency coordination efforts, and initiatives of the Office of Medical Marijuana.

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. While the Governor suspended the establishment of three compassion centers, one in each county, in February 2012, 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 a Request for Proposal (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. Appendix A, beginning on page 20, contains those correspondences.

The purpose of this report is to document the development activities of the MMP during its second year, to outline the operating efforts established and maintained during FY14, and to describe the results of those efforts. This report is submitted as required by paragraph §4922A (b)³ of the Act.

The Division of Public Health's (DPH) Health Systems Protection Section (HSP) is responsible for the policy development and operation of the MMP. Its Office of Medical Marijuana (OMM) initiated

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

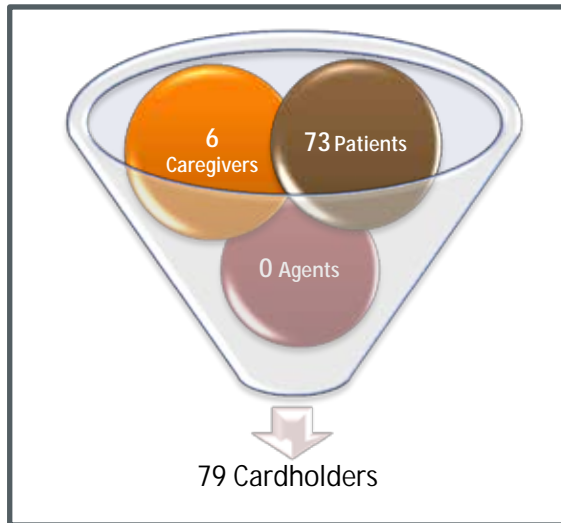
² <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf>

³ <http://delcode.delaware.gov/title16/c049a/index.shtml#4922A>

activities in August 2013 to open a pilot compassion center. Using the state’s procurement process, OMM issued an RFP for the pilot compassion center⁴ and selected the winning bidder. The process began with proposed regulation edits that were promulgated through a public comment period in October 2013⁵ and codified in the *Register of Regulations* in January 2014⁶. The revised regulations became effective January 10, 2014.

Number of Delaware Medical Marijuana Program Cardholders, July 2014

Figure 1.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

DHSS published the RFP in December 2013 and OMM held a mandatory pre-bid meeting in January 2014. DHSS received seven bid proposals in April 2014. The diverse, DHSS-selected bid review committee evaluated the proposals in May 2014 and identified a winning bid based on the RFP grading rubric. DHSS entered the contract negotiation process with FSCC in June 2014. DHSS and FSCC ratified the contract in August 2014, with plans to open the center in December 2014.

OMM continued 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.

On June 30, 2014, there were 79 active cardholders: 73 patients, six caregivers, and no agents⁷ (See Figure 1). During FY14, OMM issued 74 registration cards: 56 new patient cards, five new caregiver cards, 12 patient renewal cards, and one caregiver renewal card (See Figure 2 for comparison with the previous year). OMM has not yet issued cards to any compassion center agents (board members, owners, employees, contractors, volunteers, etc.).

Number of Delaware Medical Marijuana Registration Cards Issued, by State Fiscal Year

Figure 2.

Cards Issued	Patients	Caregivers
New FY 2013	34	1
New FY 2014	56	5
Renewal FY 2014	12	1
Total	102	7

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

⁴ http://bidcondocs.delaware.gov/HSS/HSS_13056MedMarij_rfp.pdf

⁵ <http://regulations.delaware.gov/register/october2013/proposed/17%20DE%20Reg%20405%2010-01-13.htm>

⁶ <http://regulations.delaware.gov/register/january2014/final/17%20DE%20Reg%20738%2001-01-14.htm>

⁷ As of August 2015, there were 495 active cardholders: 437 patients, 28 caregivers, and 33 agents. Some people have more than one type of card, so the sum of the types will be more than the total cardholders.

**Delaware Medical Marijuana Program
Applications Received, Processed, and
Approved, FY13 and FY14**

Figure 3.

Applications	Received	Processed	Approved
FY 2013	54	43	38
FY 2014	124	77	71
% Increase	130%	79%	87%

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

The Act established an economically self-sustaining program, but the change in its scope resulted in significant revenue reduction. Opening one pilot compassion center four years after the legislation went into effect meant that OMM did not collect the projected revenue from licensing compassion centers in three counties for the first three years. In addition, the number of fee-paying patients did not reach projections.

**Delaware Medical Marijuana Program
Applications Received by Application Fee
Paid and State Fiscal Year**

Figure 5.

	Paid \$125	Paid under \$125	Paid Full Fee
FY 2013	25	29	46%
FY 2014	74	50	60%

Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

As seen in Figure 3 on page 3, OMM received 124 applications in FY14, an increase of 130 percent over the previous year. DHSS reviewed 77 applications during the year, and approved 71 of them. Fifty-one applications remained in processing on June 30, 2014.

DHSS denied 11 patient applications during FY14, compared to one denial the previous year. Reasons for the denials included incomplete applications and non-qualifying signatures on physician certifications (such as out-of-state doctors or physician assistants). See the Program Participation Analysis section of this report, on page 9, for more information.

**Delaware Medical Marijuana Program
Revenue and Expenses, FY13 and FY14**

Figure 4.

State FY	Revenue	Expenses
2013	\$3,500	\$119,500
2014	\$44,320	\$133,013

Source: Delaware's First State Financials (FSF) System, 2014.

The state budget allocated \$480,100 Appropriated Special Fund (ASF) spending authority for annual program operation. Program expenses for Delaware State Fiscal Year 2013 (FY13) totaled \$119,500, while revenue was \$3,500. Program expenses for FY14 were \$133,013; revenue was \$44,320. (See Figure 4.) Program revenue did not cover FY13's expenses, but it did pay for almost \$6,000 of FY14's expenses.

HSP assisted the MMP with expenses detailed in the Financial Analysis section of this report. The Office of Management and Budget (OMB)

temporarily moved the two existing program’s budget positions, Administrative Specialist II and Public Health Treatment Program Administrator, to General Funds.

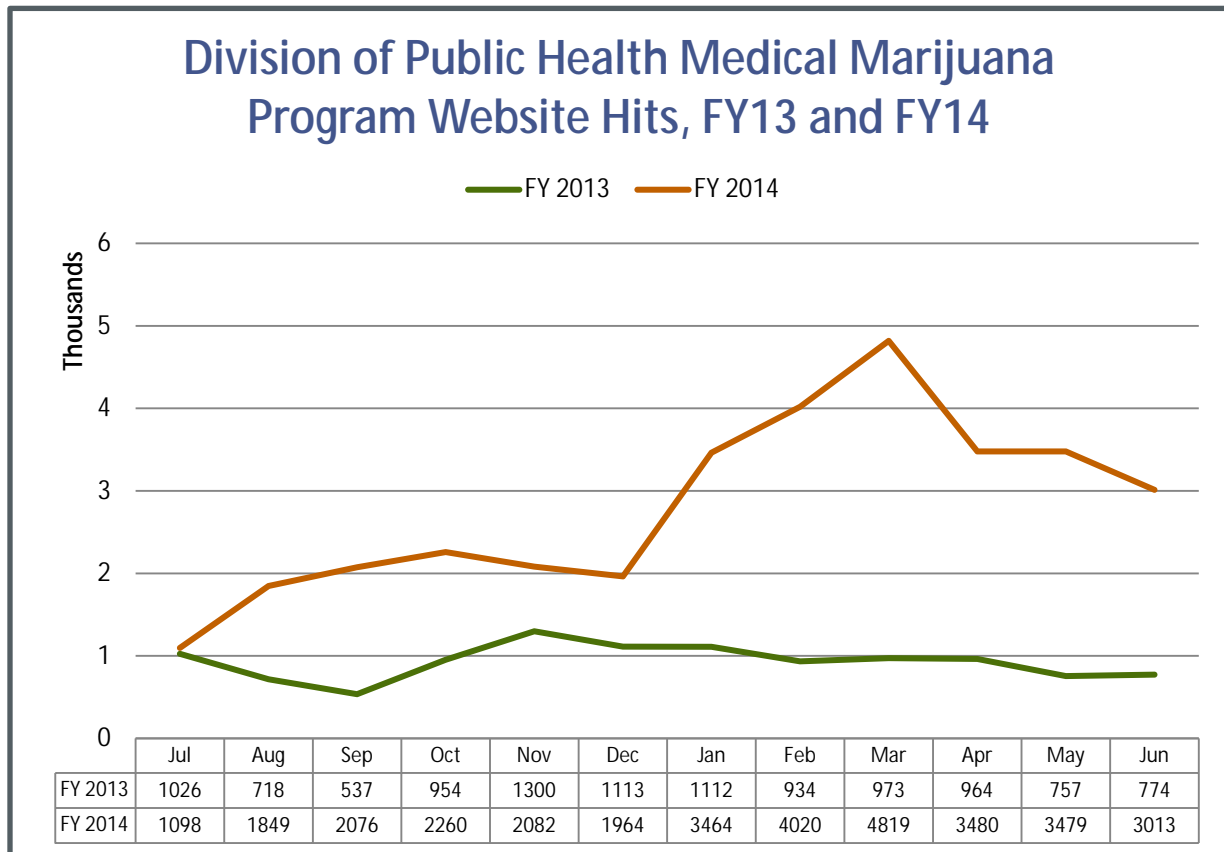
Program revenue increased significantly in FY14 due to \$35,000 received from RFP application fees. Seven vendors submitted a proposal for the compassion center, each paying a \$5,000 application fee.

The patient and caregiver registration fee remained at \$125 per 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. The sliding scale figures used are available in Appendix B on page 27. OMM received a significant number of applications without the full fee of \$125. Many of the applicants qualified to have the fee waived, while some qualified for a reduced fee. The percentage of applicants paying the full application fee increased to 60 percent in FY14, compared to 46 percent in FY13. (See Figure 5.)

III. Education and Outreach

There are two primary ways that stakeholders and constituents can contact OMM with questions about the MMP: a dedicated program phone number, 302-744-4749, and the program’s resource e-mail

Figure 6.



Source: Delaware Health and Social Services Internet Site Website Statistics, Fiscal Years 2013 and 2014.

account, MedicalMarijuanaDPH@state.de.us. As interest in the program increased, OMM began exploring other opportunities for sharing information. OMM contacted the Delaware 211 call center to update MMP information in their records.

As part of a communications outreach initiative in conjunction with DPH's Office of Health Risk Communications (OHRC), OMM developed Frequently Asked Questions (FAQs) for patients, physicians, and law enforcement, now available in brochures and on-line. The FAQ sheets discuss how to apply for the program, a list of qualifying debilitating medical conditions, the compassion center where patients can purchase medical marijuana, possession limits, caregiver responsibilities, and other protections, restrictions, and limitations.

OMM collaborated with OHRC, the Medical Society of Delaware (MSD), and the University of Delaware's Center for Drug and Health Studies (UD-CDHS) to identify ways to open communications with Delaware physicians and seek feedback. The multi-agency team planned for one edition of MSD's *Delaware Medical Journal* to be dedicated to medical marijuana articles. UD-CDHS developed a survey to collect information from Delaware physicians about their knowledge and opinions on marijuana as a medical treatment. In early FY15, the agencies decided to distribute the survey as part of the *Delaware Medical Journal* marijuana edition, which was published in November 2015. MSD would collect the data, and UD-CDHS would evaluate it. The suggested survey questions are in Appendix C. The FY15 annual report will include the published survey.

OMM updated the program's web page. The update included a list of application process questions with answers, information about the upcoming compassion center, a link to the RFP, and links to the application forms. The program web page address⁸ remains the same, organized under HSP's website. Figure 6 on page 4 shows the number of hits per month on the program web page and compares the figures across the two fiscal years the web page has been online. The peak in the graph coincides with the RFP proposal due date.

IV. Compliance Activities

The goal to establish a pilot compassion center in Delaware for active qualifying patients to safely access quality medical-grade marijuana primarily drove OMM's FY14 activities. Various areas of development were required, including staffing changes, regulation edits, procurement activities, and exploration of affordable information technology solutions.

Staffing

Opening a compassion center required hiring the two additional staff members projected in the OMM's August 2013 fiscal note. The MMP needed a Management Analyst II to establish and monitor the procurement process; ensure contract compliance; provide for program budgeting and fiscal

⁸ <http://dhss.delaware.gov/dhss/dph/hsp/medmarhome.html>

compliance; prepare required financial, analytical, narrative, and statistical reports; and ensure compassion center compliance with the law and regulations. The MMP needed an Investigator to ensure application compliance with the Act and regulations; conduct background checks; educate and coordinate law enforcement efforts; conduct investigations; prepare investigative reports; establish inspection criteria; and monitor compassion center compliance with safety and security standards.

OMB approved these positions in February 2014 and posted the recruitment notice for them in March. OMM interviewed in April 2014 and hired the employees in May. OMM anticipates that the positions will require at least partial funding through General Funds until the program can fully sustain them. The OMM Investigator began work in June 2014. The previous Administrative Specialist (AS) for the program, who began additional analytical work in May 2014, filled the Management Analyst position. OMM requested that the AS position be re-posted to return the team to the needed four staff members. OMB approved, and the AS position was filled in September 2015.

Regulations

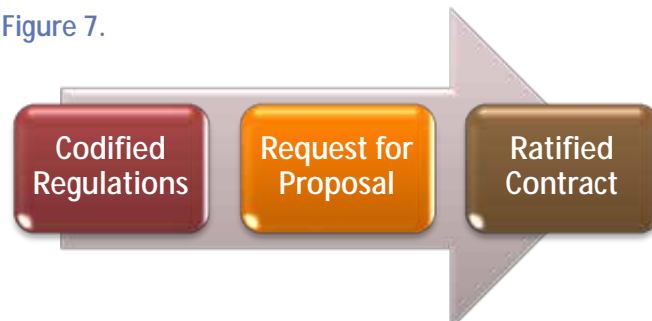
OMM drafted regulation edits that included registering and operating compassion centers; adding a debilitating medical condition; clarifying the definition of “post-traumatic stress disorder”; and removing reference to “visiting qualifying patients.” Delaware’s October 2013 *Register of Regulations* (Volume 17, Issue 4⁹) contains the edits for public comment in the Proposed Regulations section. OMM announced the Proposed Regulations in newspapers prior to the publication, as required. DPH collected

comments on the proposed regulations during October 2013. Delaware’s January 2014 *Register of Regulations* (Volume 17, Issue 7¹⁰) contains the comments and DHSS responses. The codified regulations are included in Section 4470 of Title 16¹¹ of Delaware’s Administrative Code.

As directed by the state executive leadership, the pilot compassion center would be limited to a maximum plant count of 150 and a maximum useable marijuana store of 1,500 ounces, regardless of formulation. Section 7.2.6 of the adopted regulations outlines these limits.

Delaware Medical Marijuana Program Focus FY14 – Establish a Pilot Compassion Center

Figure 7.



Source: Title 29 DE Code, Chapter 69: State Procurement.

⁹<http://regulations.delaware.gov/register/october2013/proposed/17%20DE%20Reg%20405%2010-01-13.htm>

¹⁰<http://regulations.delaware.gov/register/january2014/final/17%20DE%20Reg%20738%2001-01-14.htm>

¹¹ <http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Division%20of%20Public%20Health/Health%20Systems%20Protection%20%28HSP%29/4470.shtml>

Request for Proposal and Contract

OMM began drafting RFP# HSS 13 056¹² for the Registration and Operation of a Medical Marijuana Compassion Center in the State of Delaware in August 2013, and submitted the final draft to DPH's Support Services in November 2013. On December 26, 2013, DHSS posted it on the state procurement portal at mymarketplace.delaware.gov. DHSS collected questions from potential vendors regarding the RFP until mid-January 2014, per the RFP published schedule.

On January 31, 2014, OMM held a mandatory pre-bid meeting for anyone wishing to submit proposals. Forty-two people, some representing 26 organizations, attended. 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 March.

Also in March 2014, DHSS selected members for a proposal review committee who would 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 seven bid proposals in April 2014, and the seven-member committee reviewed them the following month. DHSS notified the winning bid vendor, FSCC, and began contract negotiations with them. Due to the level of detail work that is involved with the contract, DHSS moved the contract start date from June 2014 to August 2014.

Program Development

Program development during FY14 focused on three areas of concern. The first was quality control and testing marijuana sold by the compassion center. OMM began to explore protocols for that process. The second was the need to increase MMP registration card security. Procurement of a system to produce more secure MMP registration cards was required. These new (Generation II) cards would include barcoding and embedded security features to minimize potential forgery. The third area of concern in program development was facilitating the secure transfer of large electronic application files for review from OMM (located in Kent County) to the DHSS Office of the Secretary (located in New Castle County).

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 areas like safe and efficient

¹² http://bidcondocs.delaware.gov/HSS/HSS_13056MedMarij_rfp.pdf

cultivation, harvesting, packaging, labeling, and distribution of marijuana; best security practices; inventory accountability procedures; and up-to-date scientific and medical research findings related to medical marijuana. Because the program has a reduced scope and only one pilot center, the compassion center will assume safety compliance tasks, including adequate testing of marijuana produced for sale. The contract with FSCC established testing protocols in conjunction with DHSS.

In August 2013, DPHL and OMM hosted a conference call with testing experts from a California lab to discuss the direction of marijuana testing in state programs. Several states are establishing testing protocols. The group recommended testing three samples per five pounds of harvested product. One comprehensive testing panel would cost approximately \$200. If the compassion center tested three samples out of every five pounds produced, the testing cost is below 2 percent of the gross. While there is no industry standard, the DPHL agreed to work with the program and FSCC to establish a best practice going forward.

Generation II Registration Cards

OMM studied ways to increase the security on the card to prevent counterfeit reproductions. DPH already had experience with PremiSys™, a software program sold and supported by IDenticard™ Systems. This solution was affordable at approximately \$2,000. IDenticard™ Systems offers a full suite of anti-counterfeiting security features that would allow OMM to increase card security as program needs and the budget allow.

IDenticard™ Systems produces an inkjet-printable identification card solution called JetPaks™. These cards are made of Teslin®, a durable synthetic substrate advertised to not crack or warp. They are resistant to fading and discoloration; and create a durable, lasting card when paired with a laminate sleeve. In addition to two-sided printing options with this solution, JetPaks™ can incorporate several additional features to increase security. OMM opted to have a barcode strip included on the MMP *Generation II* cards so compassion center staff can scan them.

OMM submitted a Project Charter to IRM for a stand-alone card generation system, including the PremiSys™ software, in March 2014. The DHSS IRM Technical Review Committee approved the charter in April 2014. OMM ordered the equipment, which arrived in May 2014. Additional software functionality would benefit the program if the architecture included a network database. OMM began gathering information about this additional functionality.

**Delaware Medical Marijuana Program
Registration Card Logo**

Figure 8.



Source: Delaware Health and Social Services, Division of Public Health, Delaware Office of Medical Marijuana, 2014.

OMM coordinated new card templates and artwork with OHRC and IDenticard™ Systems. The team designed a program logo (See Figure 8) and other images for use with the proprietary IdentiGuard™ feature on the cards. Once the template design was complete and approved, OMM ordered the JetPaks™ to produce the new cards before the compassion center opened.¹³

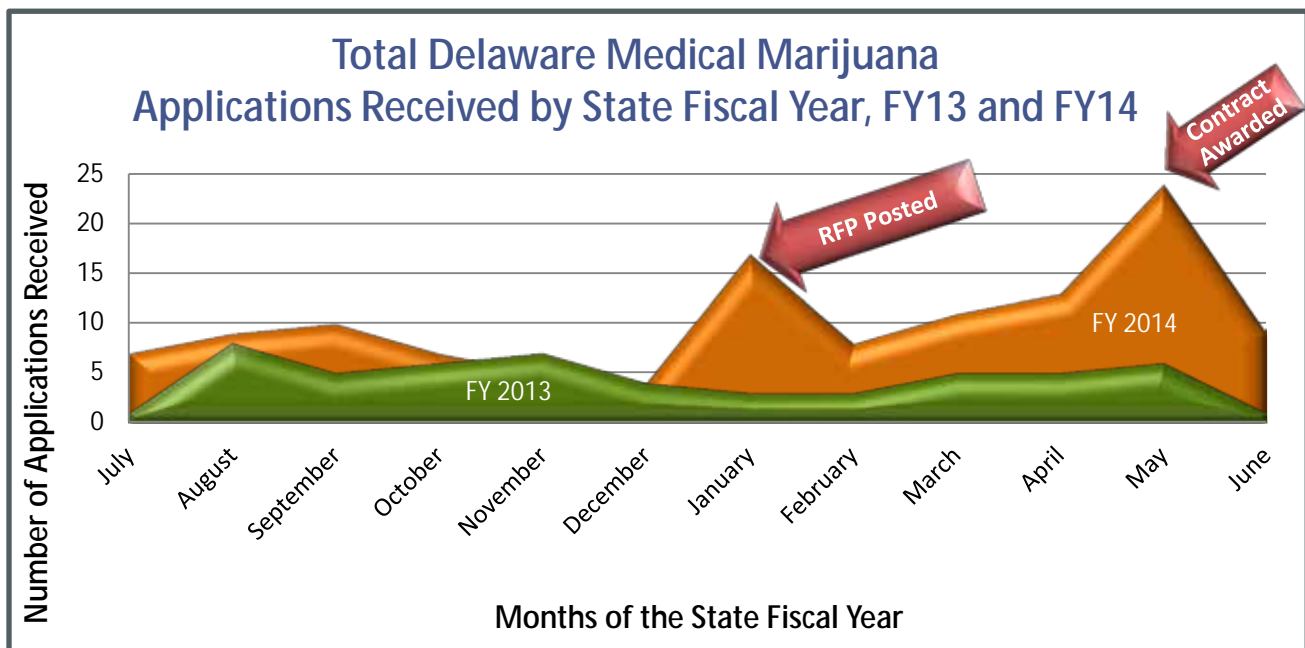
Secure File Transfer for Application Review

The MMP application approvers are located in Kent County and New Castle County. OMM began transfer of the very large scanned applications by email. To avoid over-filling email accounts, OMM requested a Secure File Transfer Protocol (SFTP) folder to send the application files from OMM to DHSS for review. As of June 30, 2014, OMM awaited final approval and set-up of that protocol.¹⁴

Program Participation Analysis

OMM tracks program participation data in two ways: applications received and individual applicants. The application figures relate the volume of OMM work, while the applicant figures give perspective to the number of people who applied for registry cards. OMM processes applications from three kinds of applicants: new applicants, renewing applicants, and previously denied applicants. OMM also processes

Figure 9.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

¹³ As of August 2015, all cardholders have the new, more secure, registration cards. First template card production has ceased.

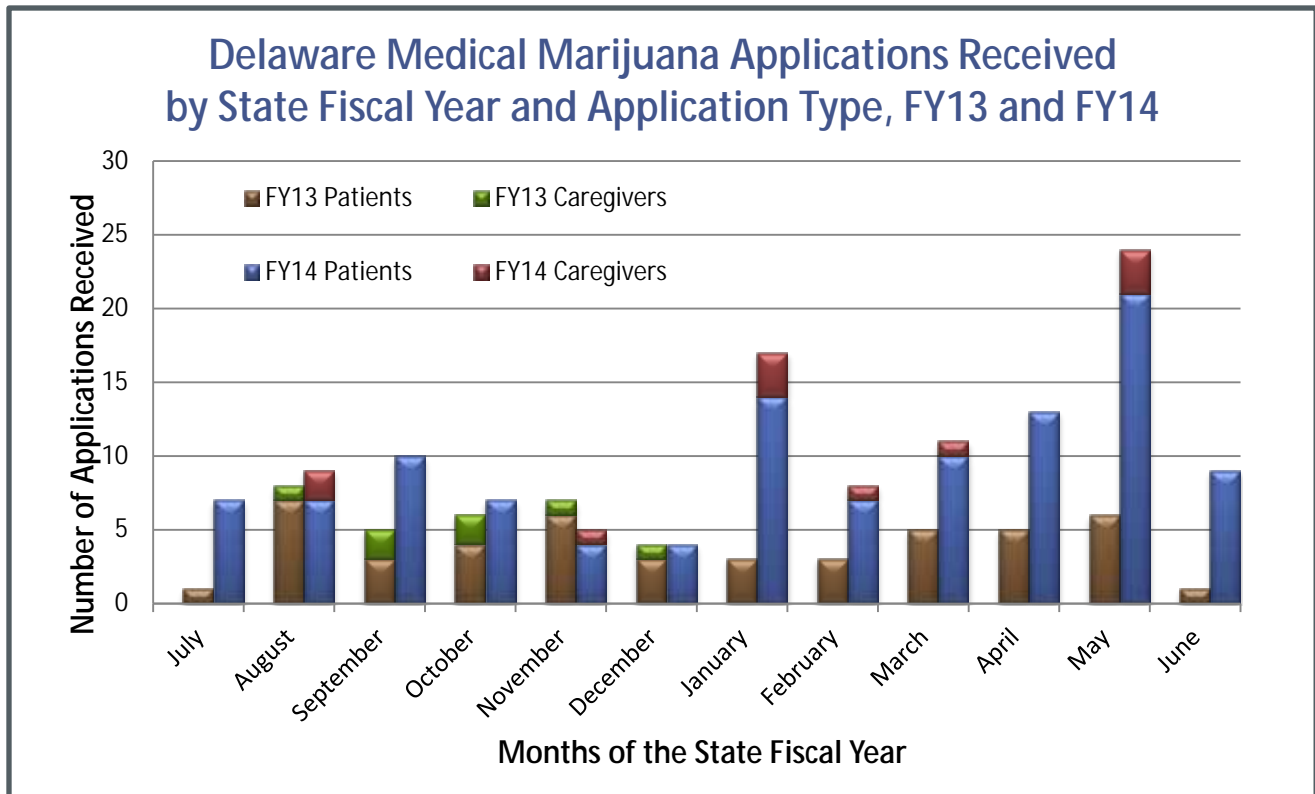
¹⁴ As of August 2015, the two offices use the SFTP to transfer files.

application modifications for changes in applicant information or replacements for lost or stolen cards. Each applicant could have multiple applications submitted. As a result, the number of application instances will never reconcile with the number of applicants; they are two different entities with two different scopes.

Application Volume

Total Applications Received

Figure 10.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

OMM received 124 registry card applications in FY14, 130 percent more than FY13. January and May 2014 were the busiest and accounted for most of the increase in volume for the year. These months coincided with the publication of the RFP for the compassion center and the announcement of the vendor for that contract. Figure 9 on page 9 shows the application volume comparison between the two years. It also notes corresponding events related to the opening of the compassion center. The data in Figure 9 includes all the applications received from patients, caregivers, and compassion center agents.

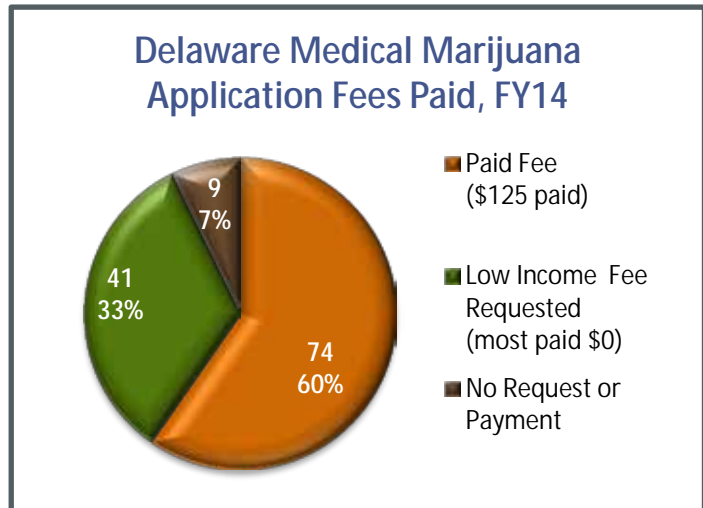
Figure 10 on Page 10 shows the same data displayed a different way. In this chart, the stacked bars itemize application types that make up each of the data points. The first stacked bar in each cluster represents FY13 data. Each color is a different type of application received: patient or caregiver. The

second bar in each cluster is FY14 data, again with each color representing a different type of application. Each cluster represents a month of the state fiscal year.

Application Revenue

As shown in Figure 11, 60 percent of the applications received during FY14 included the full \$125 application fee. Thirty-three percent included a request for a low-income application fee. OMM approved two of these requests for a partial payment based on the sliding income scale. The other low-income requests qualified to have the fee waived (\$0 payment). Seven percent of applications received had no payment and no requests for low-income consideration. In FY13, OMM processed 54 percent of the applications with no payment; that number declined to 40 percent in FY14. The number of applications OMM processes with no fee, even if denied, affects the projected revenue generated from the application fees.

Figure 11.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

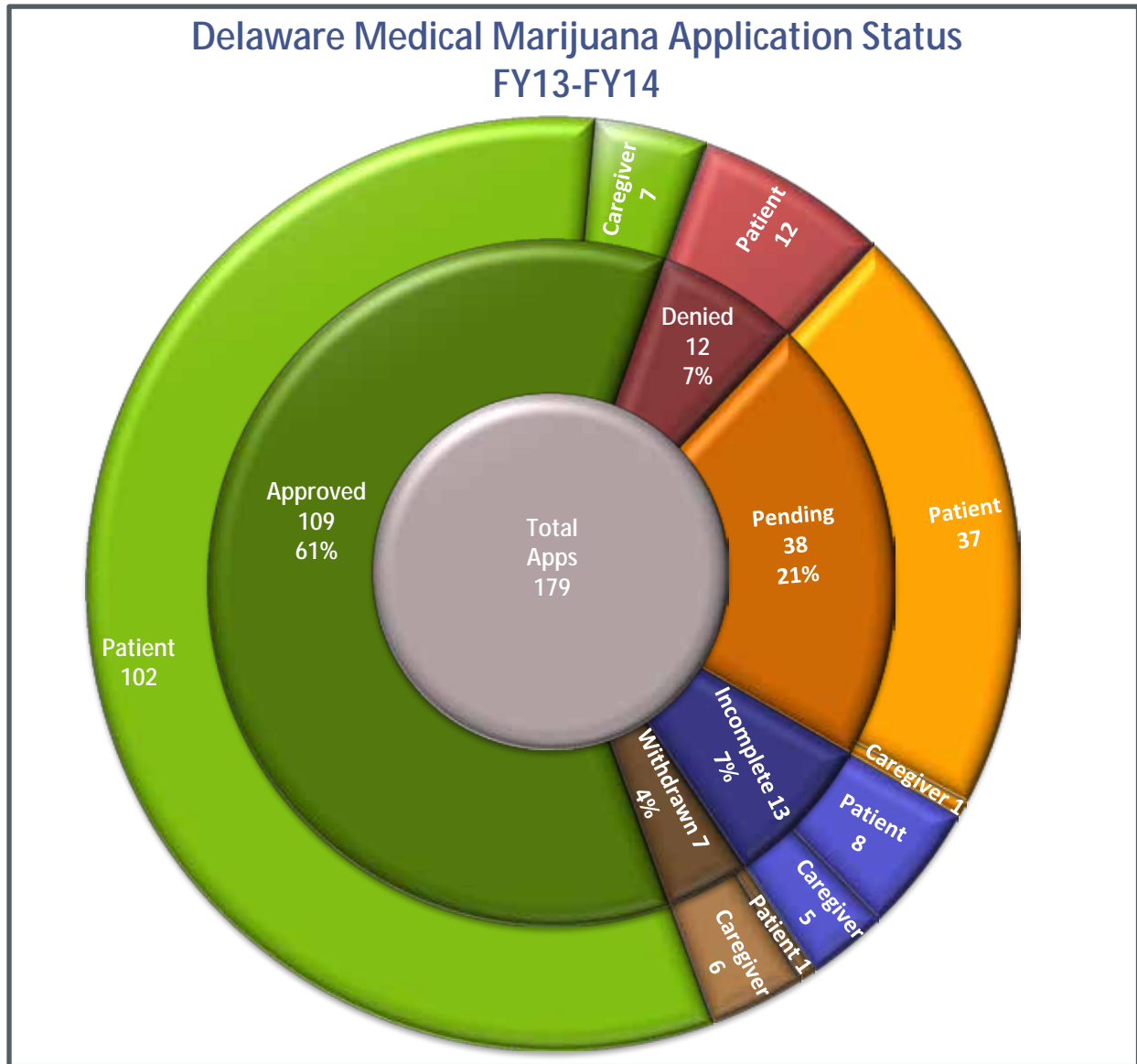
Year End Application Status

Figure 12 on page 12 shows the status, at the end of FY14, of the total applications submitted to OMM since the beginning of the program. DHSS approved 61 percent of the submitted applications and denied 7 percent. Twenty-one percent of the applications were still in processing at the end of FY14. Some were waiting for physicians to verify their certification, while others were in the signature process. The application reviewers are the Program Manager, HSP Section Chief, DPH Director, and the DHSS Secretary.

The submitted applications varied in type. Twenty-one applicants submitted renewal applications (one was a caregiver), and 158 applicants submitted new applications (18 were caregivers). One patient, who lost her registration card, submitted an application modification. DHSS has not revoked any cards. One patient withdrew her registration due to legal concern for her children. Six caregivers withdrew applications due to financial concerns.

DHSS denied 12 applications for various administrative reasons. Seven were incomplete. Five 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.

Figure 12.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

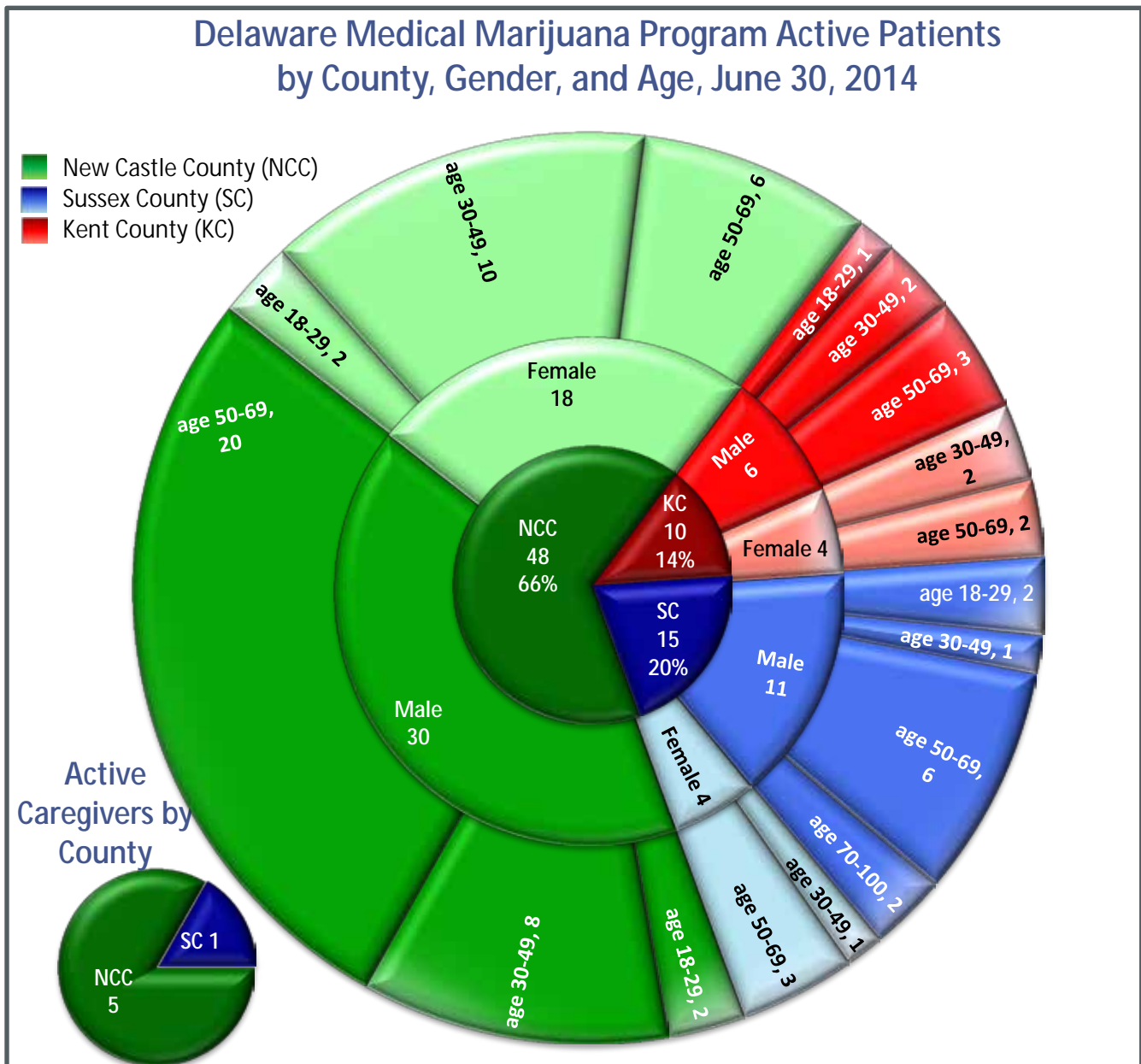
Participant Volume

Active Participant Demographics

Since the beginning of the program, 154 applicants had applied for MMP registry cards. Seventy-three patients and six caregivers (52 percent of applicants) were active at the end of FY14. Seventeen applicants had expired cards and have not submitted a renewal application. DHSS denied 11 applicants and they have not reapplied. Six withdrew their applications. Forty-two have applications in process. One caregiver applicant passed away before OMM received their background check.

Figure 13 on page 13 shows the 73 active patients at the end of FY14 by county, gender within county, and age within gender. They include residents in all three counties, both genders, and ages 22 to 81. Two-thirds of the patients live in New Castle County. Male patients outnumber female patients by 2:1. The average patient age is 51 years old. Figure 13 shows active caregivers by county.

Figure 13.

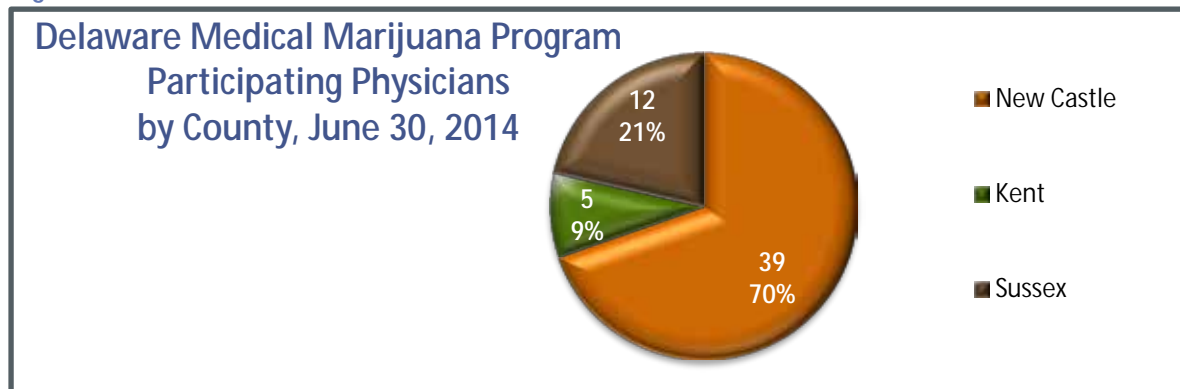


Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

Participating Physicians

As of June 30, 2014, 56 physicians had participated 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. Thirty-nine participating physicians have offices in New Castle County, 12 have offices in Sussex County, and five have offices in Kent County. (See Figure 14)

Figure 14.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

Active Patient Debilitating Conditions

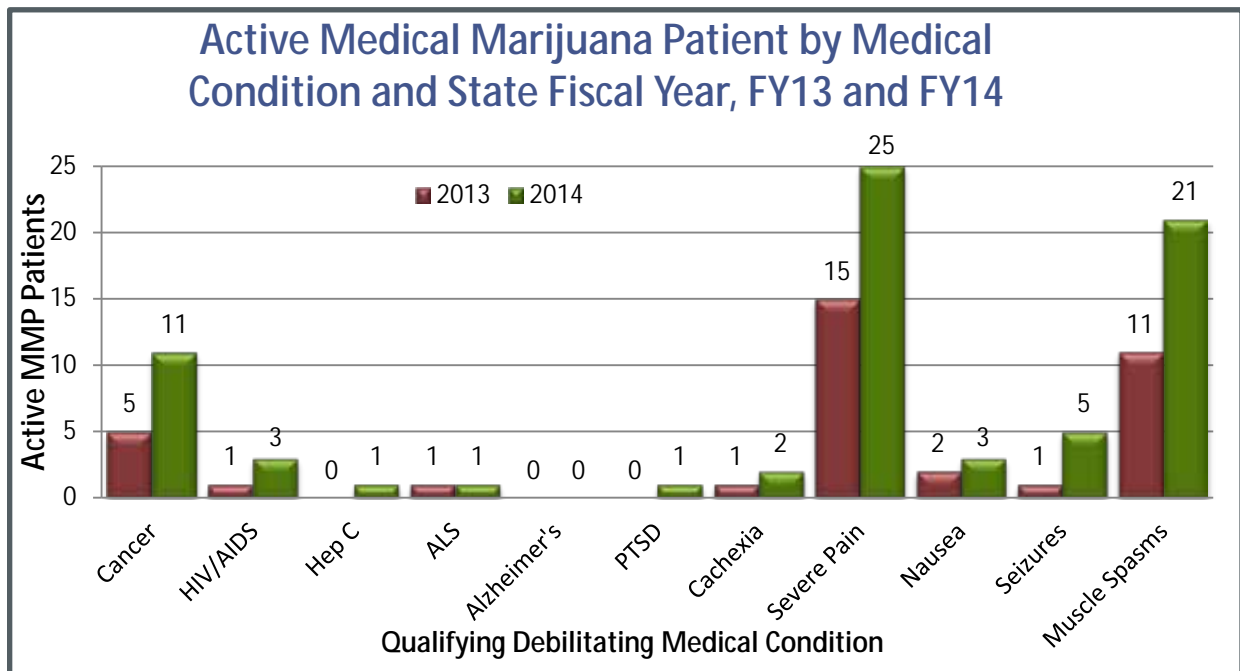
MMP qualifying debilitating medical conditions are listed in section 2.0 Definitions of the regulations¹⁵. That list currently includes:

- The following medical conditions or treatment of these conditions:
 - cancer;
 - positive status for human immunodeficiency virus (HIV);
 - acquired immune deficiency syndrome (AIDS);
 - decompensated cirrhosis (hepatitis C);
 - amyotrophic lateral sclerosis (ALS or Lou Gehrig's Disease);
 - post-traumatic stress disorder (PTSD); and
 - agitation of Alzheimer's disease; or

¹⁵ [http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Division%20of%20Public%20Health/Health%20Systems%20Protection%20\(HSP\)/4470.shtml#1057590](http://regulations.delaware.gov/AdminCode/title16/Department%20of%20Health%20and%20Social%20Services/Division%20of%20Public%20Health/Health%20Systems%20Protection%20(HSP)/4470.shtml#1057590)

- 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;
 - intractable nausea;
 - seizures; or
 - severe and persistent muscle spasms, including but not limited to those characteristic of multiple sclerosis.

Figure 15.



Source: Delaware Health and Social Services, Division of Public Health, Medical Marijuana Program Database, July 2014.

The two most common debilitating medical conditions among qualifying patients were 1) severe, debilitating pain; and 2) severe, persistent muscle spasms. Figure 15 shows the number of active patients for each of the qualifying debilitating medical conditions. The number of patients with muscle spasms almost doubled in FY14, compared to FY13; many of these patients have Multiple Sclerosis. The number of patients with cancer also more than doubled during the same period.

Financial Analysis

Section §4923A (5)¹⁶ of the Act stipulates the MMP be a financially self-supported program; however, due to program scope changes, the necessary revenue has not been available. The cost of implementing the program has exceeded available resources. The program structure included issuing registration cards in addition to opening and inspecting three compassion centers and one testing facility. The first two years the program received revenue from only card application fees and RFP bid fees. Figure 16 details program revenue and expenses for FY13 and FY14.

Delaware Medical Marijuana Program Revenue and Expenses by Year, FY13-FY14

Figure 16.

FY13	Revenue	Expense
Registration Card Application Fees Paid	\$3,500	
Employee Expenses (2 FTEs)		\$90,000
Equipment (computers, camera, office security system, scanner)		\$18,000
Furniture (chairs, desks, file cabinets)		\$10,000
Services (phones, design work, delivery/set up)		\$1,000
Miscellaneous Expenses (postage, etc.)		\$500
Totals	\$3,500	\$119,500

FY14	Revenue	Expense
Registration Card Application Fees Paid	\$9,300	
Replacement Card Fees Paid	\$20	
RFP Proposal Fees Paid (7 bids, \$5,000 each)	\$35,000	
Employee Expenses (2.08 FTEs)		\$118,000
Software (PremiSys™, Adobe Acrobat)		\$2,650
Equipment (computers, card printer)		\$4,100
Services (custom die charges, design prep, legal ads, postage)		\$2,263
Supplies (card creation supplies, ink, files, etc.)		\$6,000
Totals	\$44,320	\$133,013

Source: Delaware First State Financials System, June 2014.

Program Revenue

MMP's FY13 revenue was \$3,500, all from card application fees. Without the compassion centers being open, the card demand was less than projected. OMM issued approximately half of the approved cards to applicants qualifying for the waived fee. In FY14, MMP revenue increased to \$44,320; RFP application fees generated \$35,000 of that total. OMM required a bid fee to ensure only serious vendors – with the necessary resources to establish and operate the seed-to-sale business – submitted proposals. The additional \$9,320 in collected revenue was from card application fees. Most applicants paid either the full fee of \$125 or were qualified and approved for the fee to be waived, though a few applicants fell in the middle of the sliding scale based on their income and paid a percentage of the fee,

¹⁶ <http://delcode.delaware.gov/title16/c049a/index.shtml#4923A>

such as \$50. There was only one duplicate issued card resulting in a replacement card fee. OMM did not levy any fines against cardholders in FY14.

Employee Expenses

The estimated \$480,100 in ASF spending authority was to support four full-time employees (FTE). After the Act went into effect in 2011, DPH hired a Public Health Treatment Program Administrator at paygrade 18 as the program manager. In addition, DPH hired an Administrative Specialist II (AS) at paygrade 8 to develop and process card applications, communicate with potential patients, and help design the application process.

In early 2012, state leadership suspended funding for two additional budget positions and moved funding for the two existing budget positions to General Funds. In August 2013, when they lifted the compassion center suspension, OMM received approval to hire the two additional staff members to help with the process of opening the center and to process the increased number of applications. Program revenue would fully fund the Investigator II (Paygrade 11) position and would fund 60 percent of the Management Analyst II (Paygrade 13) position. Employee costs in 2014 totaled approximately \$118,000, paid out of General Funds, compared to \$90,000 in 2013. The Investigator began working in June 2014. The previous AS began the Management Analyst II position in May 2014. OMM submitted a request to re-fill the AS position.

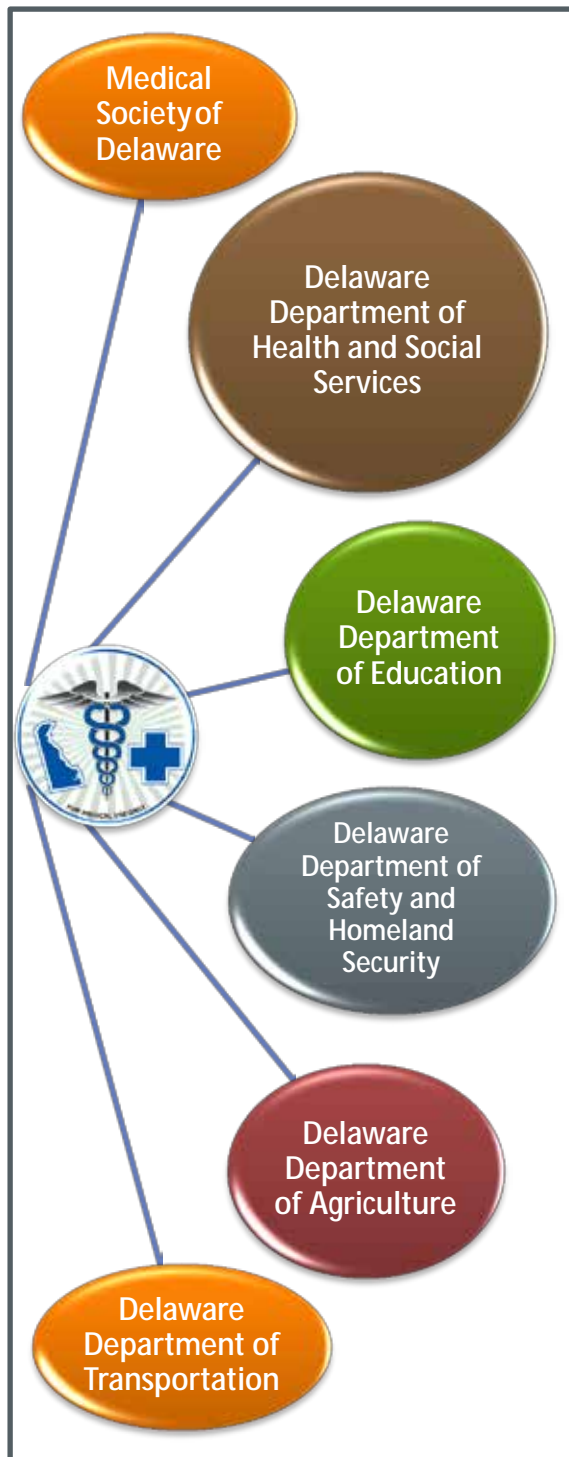
Start Up Expenses

OMM, with the help of HSP's administrative office funding, procured equipment, furniture, and supplies. This included office furniture, desktop computers, a camera, secure filing cabinets, files, registration card materials, postage, and other miscellaneous expenses. OMM also secured the office suite with a limited access security system including video monitors, in accordance with the Act.

V. Interagency Coordination

Many state agencies collaborated with OMM to open a pilot compassion center (see Figure 17 on page 18). The Delaware Criminal Justice Information System (DELJIS) staff helped provide 24-7 access to cardholder status by law enforcement; and the State Bureau of Identification (SBI), within the Department of Safety and Homeland Security (DSHS), ran background checks. The UD-CDHS, part of the Delaware Department of Education, and MSD helped to involve physicians. A team of reviewers provided insight on submitted bid proposals from various perspectives, including DSHS's Division of Gaming Enforcement (DGE), the Delaware Department of Agriculture (DDA), and other DHSS divisions. The DPHL developed testing criteria. The Delaware Division of Motor Vehicles (DMV) assisted OMM staff in verifying identification documents.

Delaware Agencies Assisting in the
Development of the Medical Marijuana
Program as of June 2014



Source: Delaware Health and Social Services,
Division of Public Health, Internal Bi-weekly Reports,

The Act requires law enforcement to be able to verify cardholders' status 24 hours a day, 7 days a week. DELJIS added a Medical Marijuana section to the CJIS (Criminal Justice Information System). OMM enters and edits cardholder data into this part of the system. DELJIS generates a report for OMM of cardholders that interact with law enforcement so OMM can ensure continued cardholder compliance.

The Act also requires a multi-jurisdictional background check for caregiver applicants. DPH coordinated efforts with SBI, which helped OMM staff understand the procedures for applying for a state background check. SBI continues to support the program by producing those reports for caregivers. They also issue a fingerprint card to the caregivers who use it to request a Federal Bureau of Investigation report.

The MSD coordinated distribution of a UD-CDHS developed physician survey querying doctors' knowledge and opinions on medical marijuana. The proposed questions are in Appendix C on page 29. OMM and CDHS forged a partnership for research purposes in hopes of gaining insight through data collection and analysis. The staff at CDHS has extensive training in quantitative and qualitative data analysis techniques and procedures; they offer rapid turn-around for data projects.

Many agencies offered staff members to help review the compassion center bids and provide a variety of perspectives. The DHSS Division of Management Services (DMS) provided administrative and information technology perspectives. DSHS provided insight into the adequacy of the bids' security plans. DHSS's Medical Director provided input from a treatment perspective. The DHSS Division of Services for Aging and Adults with Physical Disabilities (DSAAPD) provided input from the patient perspective. DPHL reviewed and commented on the adequacy of the bids' testing plans and advised OMM on requirements

covering quantity, quality, and other measures for the marijuana testing process required by the compassion center. DDA provided insight to the bids' proposed growing operation. The DMV continued to help OMM staff identify potentially counterfeit identification documents.

VI. DPH Initiatives

Moving into FY15, OMM continued to define the MMP's direction and focus. The first task was to conclude negotiations with the FSCC ratify contract DPH 15-125. Once that was complete, FSCC began developing the designated facility located on Germay Drive in Wilmington, Delaware. At the end of FY14, FSCC estimated the opening of the center to be in December 2014.

In FY15, OMM will review contract deliverables and work with FSCC to develop the testing criteria for contaminants and potency to ensure the safety of the registered patients. Audit strategies and inspection plans will be developed to ensure FSCC's compliance with the regulations and rules surrounding security, quality of product, and record tracking.

Diversion of medical marijuana to unauthorized recipients is the most difficult challenge the program faces. To prevent diversion, DHSS will work with FSCC to study consumption patterns and vigilance. OMM will offer trainings to state law enforcement to educate officers on the program's rules and regulations, and to collaborate with them on responding to any issues that may arise at the facility.

Technical developments regarding communications between OMM and FSCC will be addressed. A cardholder update file will be transferred to the compassion center for daily uploads, to ensure that they are servicing only active cardholders. OMM will write the Memorandum of Agreement to define the secure file transfer protocol, and work with DHSS's Information Resource Management (IRM) staff to create the folder for that purpose. OMM will also work with IRM to establish a way for the program staff to view FSCC's cameras for compliance of the security requirements established in the RFP. Lastly, OMM will work to finalize the DELJIS reporting capability for cardholders who have had contact with law enforcement.

OMM will streamline the application process to efficiently handle the expected increase in volume. This includes modifying the application forms to alleviate duplicate information and provide easier navigation. Issuing the Generation II registration cards will also be quicker once the PremiSys™ system is ready to use. Process analysis will include how best to manage the flow of patients in the Jesse Cooper Building in Dover during final transaction appointments.

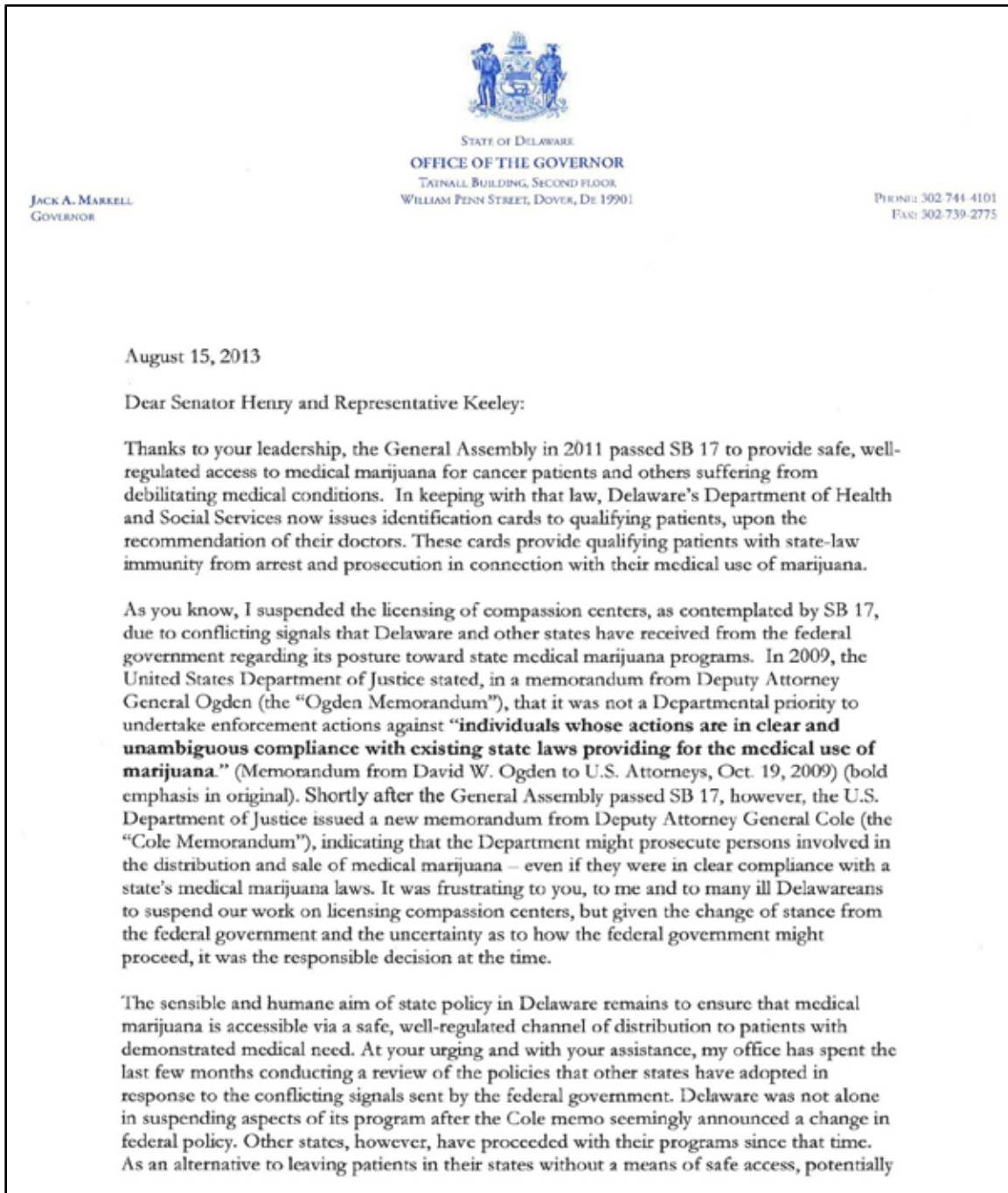
The state's leadership will seat the Medical Marijuana Oversight Committee¹⁷, as required by the Act, to oversee the program's continued development and operation. OMM will work with DHSS and other agencies as requested.

¹⁷ The Medical Marijuana Oversight Committee was finalized in September 2015. The first public meeting of the committee is being scheduled at the time of this report publishing.

Appendix A. Program Development Authorization

Governor Markell's Letter to Delaware Lawmakers announcing his intention to allow a pilot Medical Marijuana Compassion Center to open in Delaware in 2014 (Page 1 of 3)

Figure 18.



Source: from the Office of Governor Jack Markell, August 2013.

Governor Markell's Letter to Delaware Lawmakers announcing his intention to allow a pilot
Medical Marijuana Compassion Center to open in Delaware in 2014 (Page 2 of 3)

Figure 18b.

driving them into the black market, these states have chosen instead to implement their safe-access programs, while at the same time making modifications to those programs to address federal concerns. To date, states like Rhode Island and New Jersey that have taken this approach have not been subject to federal enforcement action.

As a result of our review of policies in Rhode Island, New Jersey and other states, I have become convinced that proceeding with our program, while making considered modifications to address federal concerns, is the appropriate course for Delaware. Therefore, I am writing you to inform you that DHSS will proceed to issue a request for proposal (RFP) for a pilot compassion center to open in Delaware next year.

The Cole memo expressed concern about state medical marijuana programs leading to the authorization in a state of "multiple large-scale, privately-operated industrial marijuana cultivation centers" with "revenue projections in the millions of dollars based on the planned cultivation of tens of thousands of cannabis plants." To address that concern, regulations that will be proposed by DHSS in the coming months, besides authorizing at this point only a single pilot compassion center, will limit Delaware's pilot compassion center to the cultivation of no more than 150 plants and an on-site inventory of no more than 1,500 ounces of medical marijuana. This is similar to limits on compassion centers put in place in states like Rhode Island and New Mexico to respond to the Cole memo's concern about the authorization of multiple large-scale centers in a single state.

To address the concern implicit in the Cole memo that marijuana authorized for medical use might be diverted to the black market, DHSS's proposed compassion center regulations will also include tight security requirements. Among other requirements, the pilot compassion center's facility will be subject to 24/7 video monitoring. The center will be required to verify patient and caregiver identification cards via a phone and/or online verification system before dispensing marijuana and to keep books and records in compliance with generally accepted accounting principles. The proposed regulations will authorize DHSS to access those books and records at all time and will require the Department to conduct random inspections of the center. The compassion center will also be required to report missing marijuana within 24 hours and disclose the source of any funds over \$5,000.

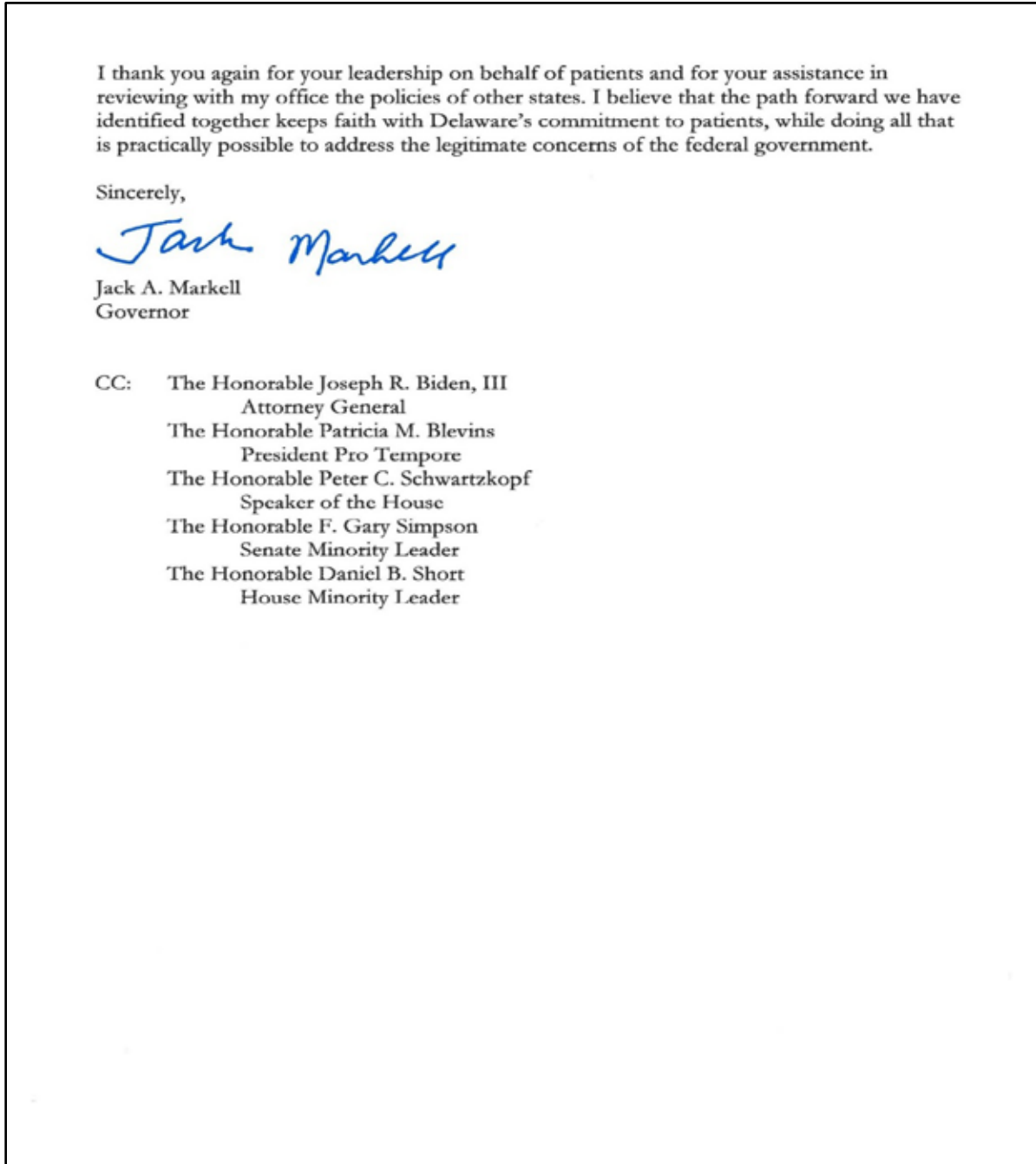
In keeping with the concerns of the federal government expressed in the Cole memo, to ensure that the medical purpose of Delaware's program is respected and maintained, DHSS will be required, before adding medical conditions for the treatment or alleviation of which medical marijuana could be authorized, to find: 1) that the medical condition is debilitating; and 2) that marijuana is more likely than not to have the potential to be beneficial to treat or alleviate the debilitation associated with the medical condition.

The legal environment in Washington and the policy landscape across the country on this issue both continue to evolve rapidly. We will continue to monitor developments as we move forward with our program in the interest of Delaware patients. It may be necessary for us to enact legislative changes to our statute in the future. I hope that, as circumstances continue to evolve, it will not become necessary once again to suspend our program, but I will not hesitate to do so should changed circumstances once again warrant it.

Source: from the Office of Governor Jack Markell, August 2013.

Governor Markell's Letter to Delaware Lawmakers announcing his intention to allow a pilot
Medical Marijuana Compassion Center to open in Delaware in 2014 (Page 3 of 3)

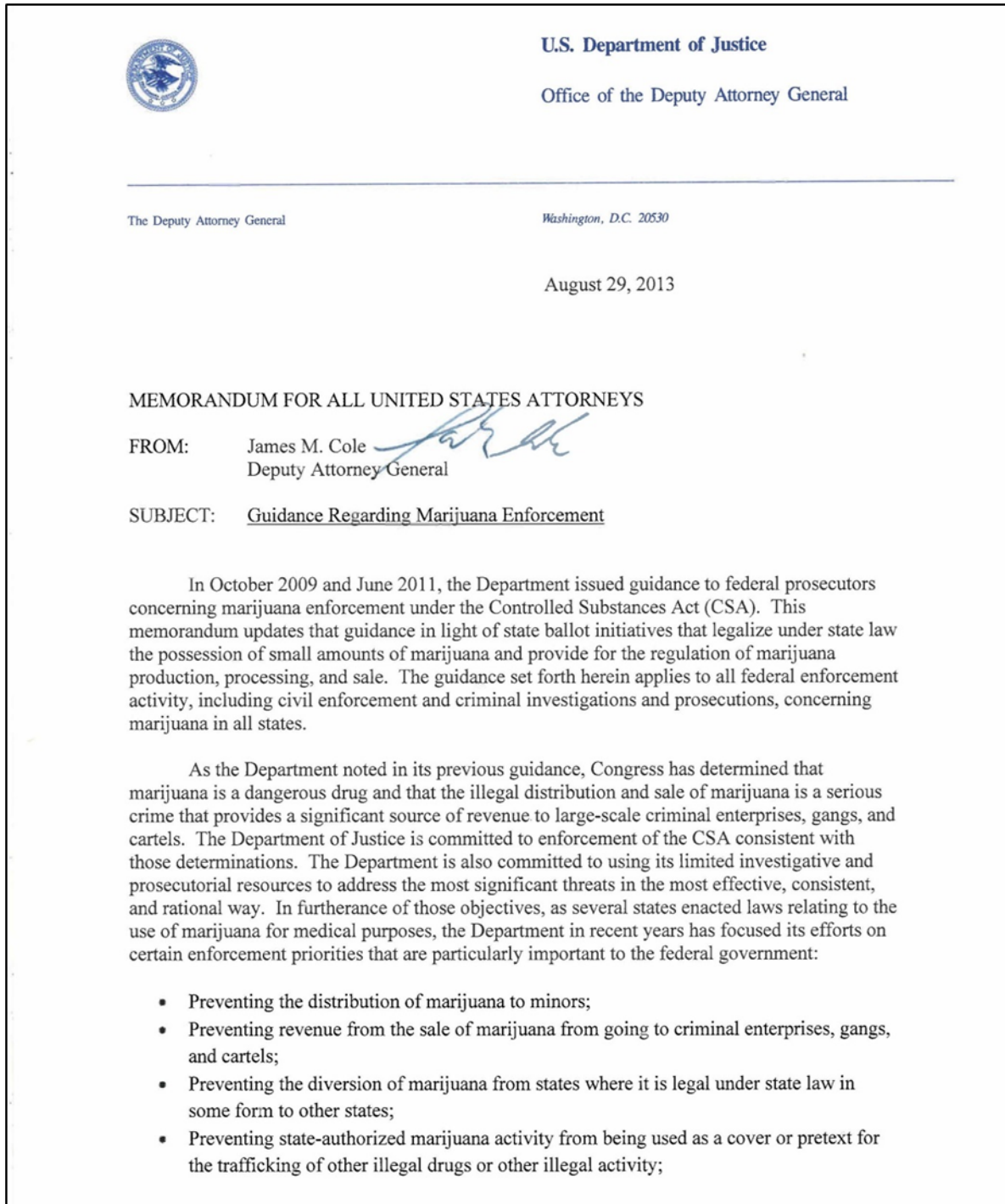
Figure 18c.



Source: from the Office of Governor Jack Markell, August 2013.

U.S. Deputy Attorney General Cole Memo providing guidance regarding marijuana enforcement
to U.S. Attorneys (Page 1 of 4)

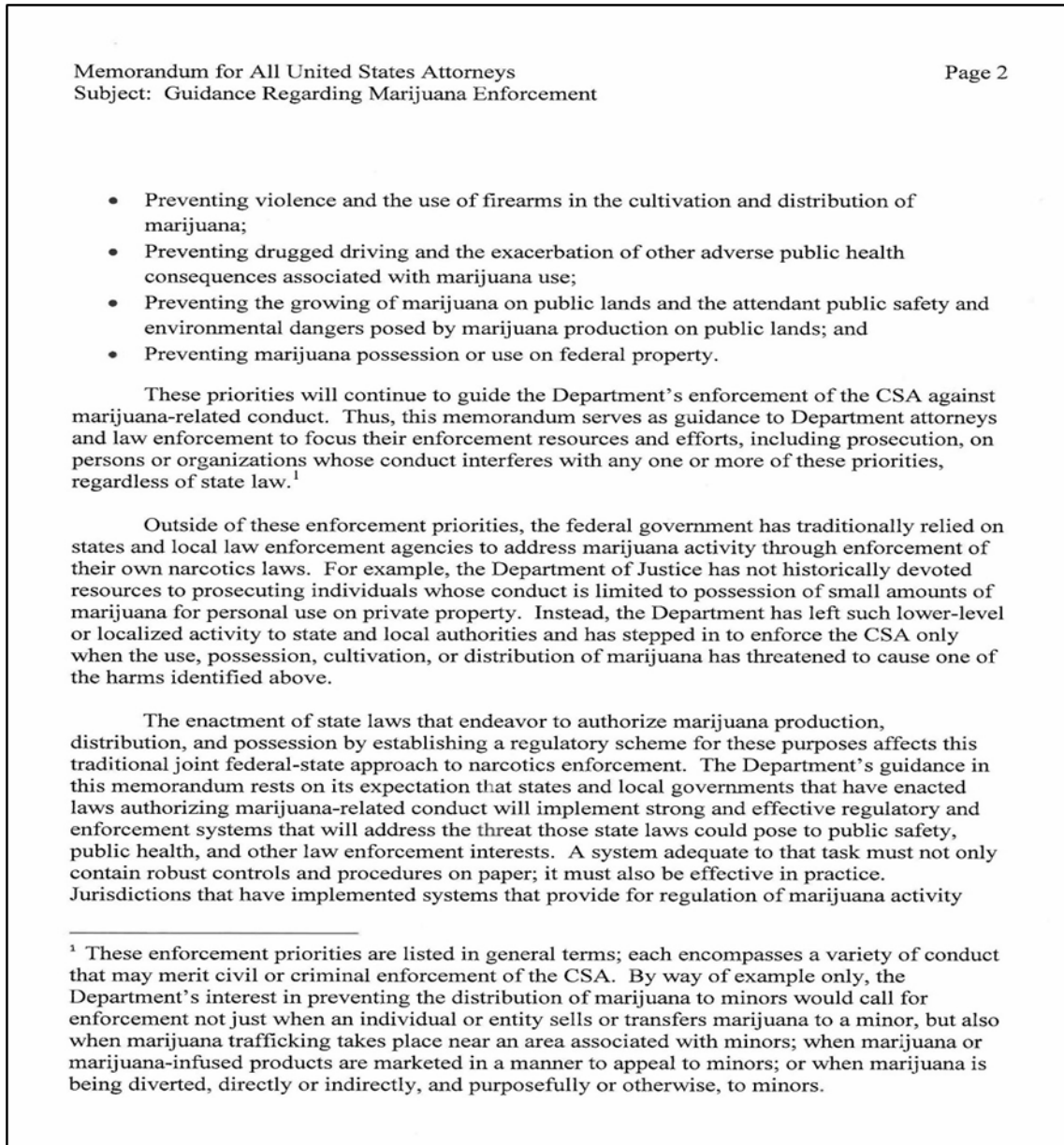
Figure 19a.



Source: U.S. Department of Justice Deputy Attorney General James Cole, August 2013.

U.S. Deputy Attorney General James M. Cole Memo providing guidance regarding *marijuana enforcement to U.S. Attorneys* (Page 2 of 4)

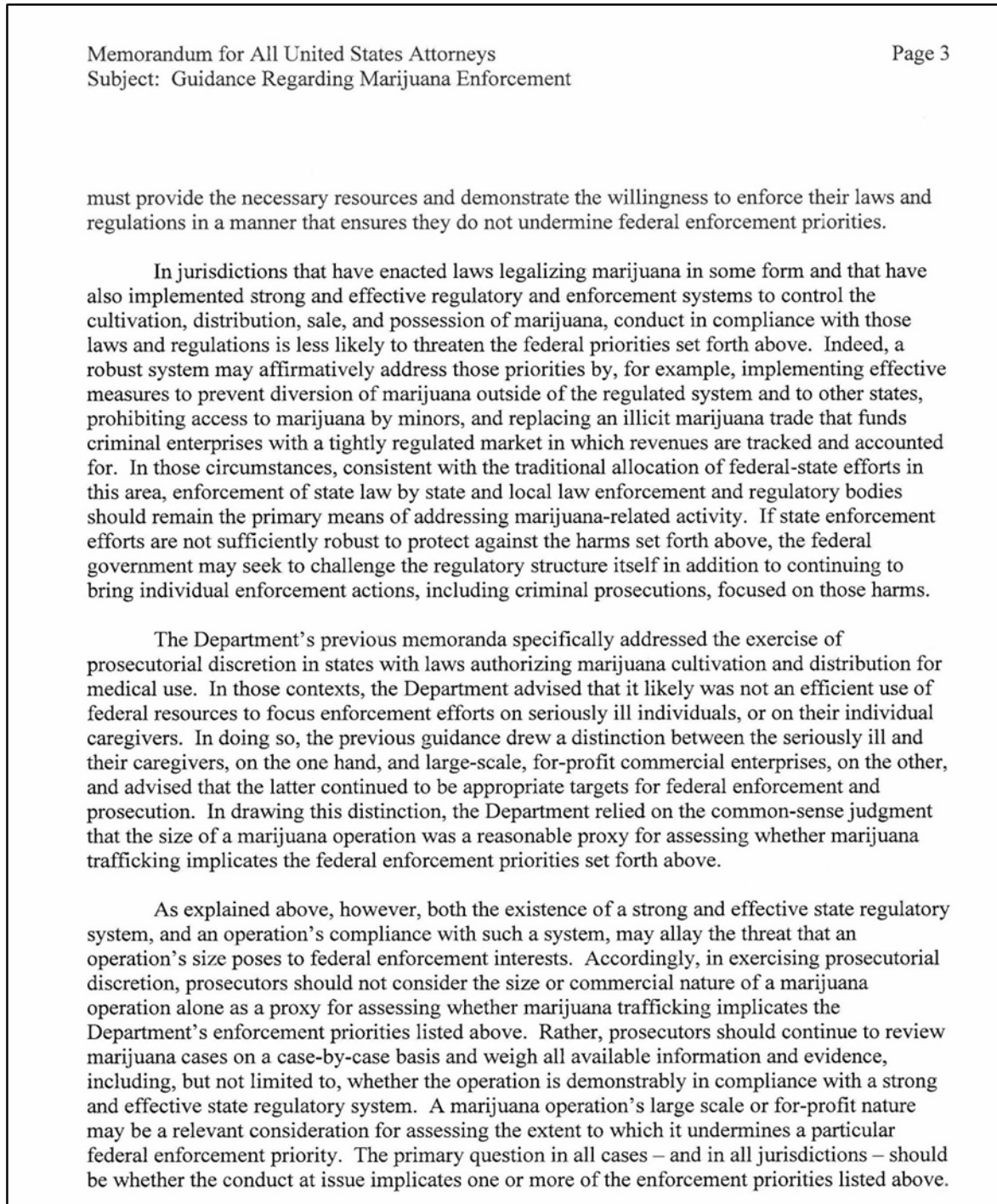
Figure 19b.



Source: U.S. Department of Justice Deputy Attorney General James Cole, August 2013

U.S. Deputy Attorney General James M. Cole Memo providing guidance regarding marijuana enforcement to U.S. Attorneys (Page 3 of 4)

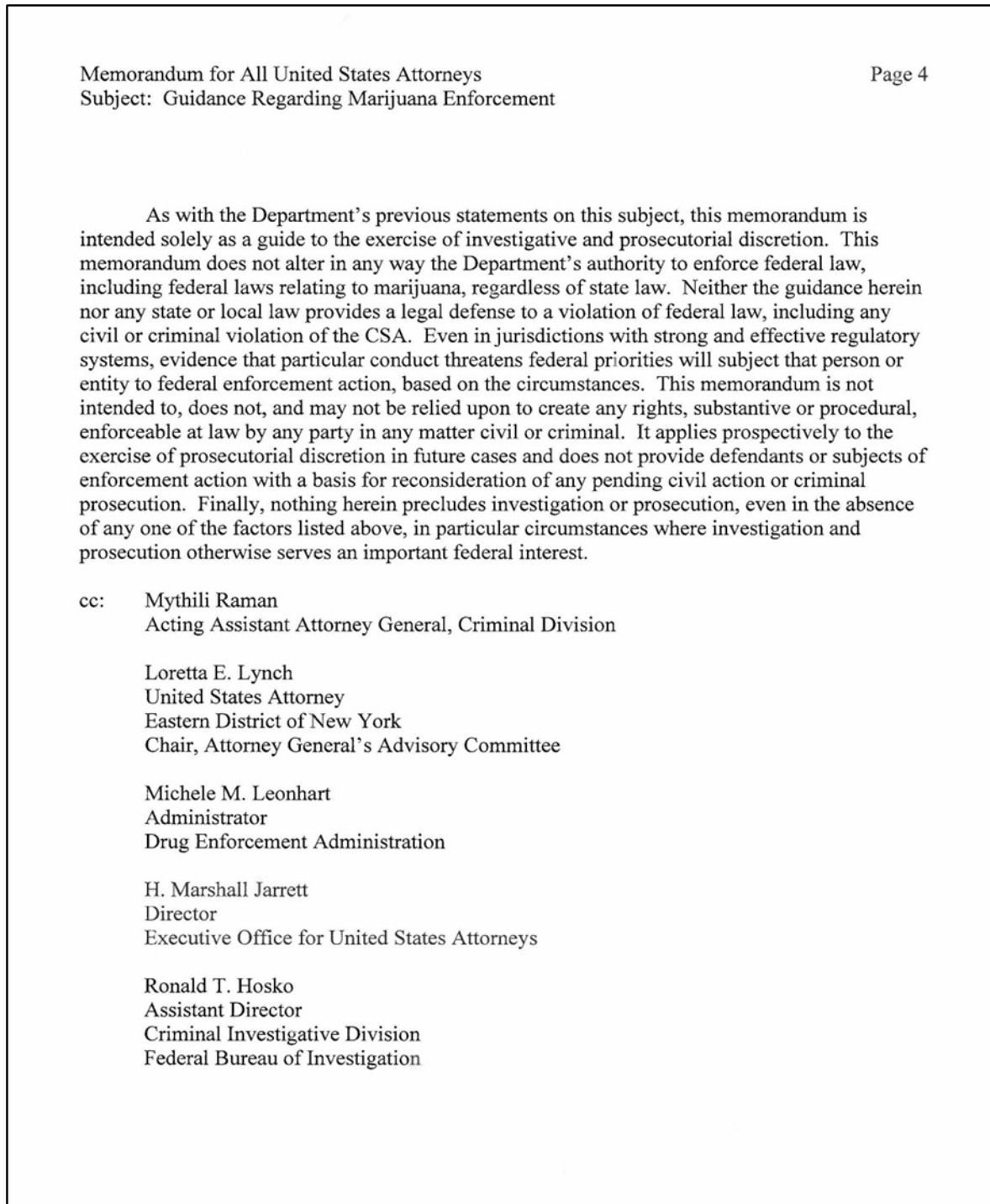
Figure 19c.



Source: U.S. Department of Justice Deputy Attorney General James Cole, August 2013.

U.S. Deputy Attorney General James M. Cole Memo providing guidance regarding marijuana enforcement to U.S. Attorneys (Page 4 of 4)

Figure 19d.



Source: U.S. Department of Justice Deputy Attorney General James Cole, August 2013.

Appendix B. Poverty Guidelines for Adjusted Application Fee

Sliding scale used to adjust application fee based on applicant's income as proven by submitted documentation. This scale was used for applications submitted prior to April 1, 2014.

Figure 20.

2013 Poverty Guidelines Set by the Federal Government							
Gross Annual Household Income up to the following % of Federal Poverty Level							
Size of Household	100%	230%	245%	260%	275%	290%	More
% increase	\$4,020						
1	\$11,490	\$26,427	\$28,151	\$29,874	\$31,598	\$33,321	\$33,321
2	\$15,510	\$35,673	\$38,000	\$40,326	\$42,653	\$44,979	\$44,979
3	\$19,530	\$44,919	\$47,849	\$50,778	\$53,708	\$56,637	\$56,637
4	\$23,550	\$54,165	\$57,698	\$61,230	\$64,763	\$68,295	\$68,295
5	\$27,570	\$63,411	\$67,547	\$71,682	\$75,818	\$79,953	\$79,953
6	\$31,590	\$72,657	\$77,396	\$82,134	\$86,873	\$91,611	\$91,611
7	\$35,610	\$81,903	\$87,245	\$92,586	\$97,928	\$103,269	\$103,269
8	\$39,630	\$91,149	\$97,094	\$103,038	\$108,983	\$114,927	\$114,927
9	\$43,650	\$100,395	\$106,943	\$113,490	\$120,038	\$126,585	\$126,585
10	\$47,670	\$109,641	\$116,792	\$123,942	\$131,093	\$138,243	\$138,243
% charges to be paid	0%	0%	20% or \$25	40% or \$50	60% or \$75	80% or \$100	100% or \$125

Source: Delaware Health and Social Services Policy Memorandum 37, updated for calendar year 2013.

Sliding scale used to adjust application fee based on applicant's income as proven by submitted documentation. This scale was used for applications submitted after to April 1, 2014.

Figure 21.

2013 Poverty Guidelines Set by the Federal Government							
Gross Annual Household Income up to the following % of Federal Poverty Level							
Size of Household	<u>100%</u>	<u>230%</u>	<u>245%</u>	<u>260%</u>	<u>275%</u>	<u>290%</u>	<u>More</u>
% increase	\$4,060						
1	\$11,670	\$26,841	\$28,592	\$30,342	\$32,093	\$33,843	\$33,843
2	\$15,730	\$36,179	\$38,539	\$40,898	\$43,258	\$45,617	\$45,617
3	\$19,790	\$45,517	\$48,486	\$51,454	\$54,423	\$57,391	\$57,391
4	\$23,850	\$54,855	\$58,433	\$62,010	\$65,588	\$69,165	\$69,165
5	\$27,910	\$64,193	\$68,380	\$72,566	\$76,753	\$80,939	\$80,939
6	\$31,970	\$73,531	\$78,327	\$83,122	\$87,918	\$92,713	\$92,713
7	\$36,030	\$82,869	\$88,274	\$93,678	\$99,083	\$104,487	\$104,487
8	\$40,090	\$92,207	\$98,221	\$104,234	\$110,248	\$116,261	\$116,261
9	\$44,150	\$101,545	\$108,168	\$114,790	\$121,413	\$128,035	\$128,035
10	\$48,210	\$110,883	\$118,115	\$125,346	\$132,578	\$139,809	\$139,809
% charges to be paid	0%	0%	20% or \$25	40% or \$50	60% or \$75	80% or \$100	100% or \$125

Source: Calculated based on Delaware Health and Social Services Policy Memorandum 37, updated for calendar year 2014.

Appendix C. Proposed Physician Survey Questions

Below are questions aimed at better understanding physicians' position and knowledge regarding medical marijuana and medical marijuana policy in Delaware. This short survey should only take 5-10 minutes to complete and your answers are completely confidential and will not be shared with your practice.

Specialty: _____

- 1) Which County do you practice in (please circle one):
 - a) New Castle
 - b) Kent
 - c) Sussex
- 2) Gender (please circle one):
 - a) Male
 - b) Female
- 3) Age:
 - a) 25-35
 - b) 36-45
 - c) 46-55
 - d) 56-65
 - e) 66+
- 4) Years practicing:
 - a) 1-10
 - b) 11-20
 - c) 21-30
 - d) 31-40
 - e) 40+
- 5) Please indicate your sources of information about medical marijuana (please circle **all** that apply)
 - a) Medical Literature
 - b) Experience with Patients
 - c) News Media
 - d) Other Physicians
 - e) Lectures/Seminars
 - f) CME
 - g) DHSS
 - h) Friends/Family
 - i) Practice Policy
 - j) Other please specify:
- 6) Please use a scale of 1 to 5 (1 being strongly disagree/very unlikely/very minimal knowledge and 5 being strongly agree/very likely/very knowledgeable) to answer the following questions.
 - a) At this time, how would you rate your knowledge about medical marijuana as a treatment option? Please circle one:

1 2 3 4 5

- b) At this time, how would you rate your knowledge about the Delaware Medical Marijuana Act, which became effective July 1st 2012? Please circle one:

1 2 3 4 5

- c) At this time, how comfortable do you feel authorizing patients to use medical marijuana (to treat specified ailments)? Please circle one:

1 2 3 4 5

Please elaborate on your selection:

- d) At this time, if your patient presented with the specified ailment(s) included in the Delaware Medical Marijuana Act, how likely would you be to authorize the use of medical marijuana as a treatment option for them? Please circle one:

1 2 3 4 5

Please elaborate on your selection:

- 7) What specific concerns, if any, do you have regarding authorizing your patients to use medical marijuana as a treatment option?

- 8) What would be helpful to you, as a physician, to learn more about medical marijuana as a treatment option and/or the medical marijuana policy in Delaware (please be specific)?