

The Department of Health Medicinal Marijuana Program

2016 Annual Report

**The Department of Health
Medicinal Marijuana Program**

This document reports the current status of the New Jersey Department of Health (Department) Medicinal Marijuana Program's (MMP) progress in the implementation of the New Jersey Compassionate Use Medical Marijuana Act (the Act), N.J.S.A. 24:6I-1 et seq. This report provides an update of program developments in calendar year 2016 on the status of the Alternative Treatment Centers (ATCs); medicinal marijuana cultivation; ATC examinations; the patient, caregiver, and physician registries; outreach and communication; education; marijuana testing; the regulatory process; and concludes with calendar year 2016 statistics (i.e., through December 31, 2016).

Alternative Treatment Centers (ATCs)

Greenleaf Compassion Center (GCC) in Montclair, Essex County, was issued a permit to cultivate on April 16, 2012, and issued a final permit on October 15, 2012. GCC began dispensing medicinal marijuana to patients on December 6, 2012. Since its initial permitting, 2,192 patients have been served, 12,083 transactions completed, and 395.45 pounds of product dispensed. From January 1, 2016 through December 31, 2016, 1,288 patients were served, 5,330 transactions completed, and 172.5 pounds of product dispensed. GCC dispensed product on 276 days in 2016. The Department maintains 24/7 video surveillance of the ATC operation and access to its internal inventory management system. GCC was re-permitted on January 1, 2016.

Compassionate Care Foundation (CCF) in Egg Harbor, Atlantic County, was issued a permit to cultivate on June 6, 2013, and issued a final permit on October 3, 2013. CCF began dispensing medicinal marijuana to patients on October 28, 2013. Since its initial permitting, 2,661 patients have been served, 26,683 transactions completed, and 967.41 pounds of product dispensed. From January 1, 2016 through December 31, 2016, 1,527 patients were served, 13,799 transactions completed, and 450.9 pounds of product dispensed. CCF dispensed product on 359 days in 2016. The Department maintains 24/7 video surveillance of the ATC operation and access to its internal inventory management system. CCF was re-permitted on January 1, 2016.

Garden State Dispensary (GSD) in Woodbridge, Middlesex County, was issued a permit to cultivate on August 7, 2013, and issued a final permit on November 20, 2013. GSD began dispensing medicinal marijuana to patients on November 22, 2013. Since its initial permitting, 4,902 patients have been served, 53,132 transactions completed, and 1843.37 pounds of product dispensed. From January 1, 2016 through December 31, 2016, 2,687 patients were served, 20,170 transactions completed, and 691.3 pounds of product dispensed. GSD dispensed product on 361 days in 2016. The Department maintains 24/7 video surveillance

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of the ATC operation and access to its internal inventory management system. GSD was re-permitted on January 1, 2016.

Breakwater ATC (BW) in Cranbury, Middlesex County, was issued a temporary permit to cultivate on November 20, 2014 and issued a final permit on October 14, 2015. Breakwater began dispensing medicinal marijuana to patients on October 15, 2015. Since its initial permitting, 2,203 patients have been served, 14,726 transactions completed, and 540.28 pounds of product dispensed. From January 1, 2016 through December 31, 2016, 2068 patients were served, 13,943 transactions completed, and 494.2 pounds of product dispensed. Breakwater dispensed product on 308 days in 2016. The Department maintains 24/7 video surveillance of the ATC operation and access to its internal inventory management system. BW was re-permitted on January 1, 2016.

Compassionate Science ATC (CS) in Bellmawr, Camden County was issued a temporary permit to cultivate on June 29, 2015 and issued a final permit on September 21, 2015. CS began dispensing medicinal marijuana to patients on September 30, 2015. Since its initial permitting, 2,870 patients have been served, 32,702 transactions completed, and 991.82 pounds of product dispensed. From January 1, 2016 through December 31, 2016, 2,762 patients were served, 31,423 transactions completed, and 884.9 pounds of product dispensed. CS dispensed product on 359 days in 2016. The Department maintains 24/7 video surveillance of the ATC operation and access to its internal inventory management system. CS was re-permitted on January 1, 2016.

Foundation Harmony (Harmony) has secured a host community in Secaucus, Hudson County. The examination of Harmony principals, corporate structure, and funding source was initiated on December 2, 2014, and is ongoing.

Medicinal Marijuana Cultivation

As a result of amendments to P.L.2009, c.307, ATCs are not limited in the number of strains of medicinal marijuana cultivated. The chart below outlines the number of medicinal marijuana strains cultivated by permitted ATCs since the inception of the program through December 31, 2016. The laboratory results of strains available are contained in the MMP Strain Library which is available to physicians and patients.

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Table 1: Medicinal Marijuana Strains by ATC

	GCC	CCF	GSD	BW	CS	Total
Total Strains Initiated	21	47	58	26	48	200
Strains Discontinued	5	10	34	6	2	57
Strains in Cultivation	16	26	20	20	46	128
Strains Tested	9	22	26	13	27	97
*CBD Strains Available	2	2	4	1	2	11
Total Strains Available	8	12	17	10	23	70

*CBD strains are, at a minimum, a 1 to 1 ratio of CBD to THC

CBD = Cannabidiol

THC= Tetrahydrocannabinol

ATC Examinations

The Department executed a Memorandum of Agreement with the Department of Law and Public Safety (LPS) on January 12, 2012. LPS agreed to assist DOH with obtaining credible and relevant criminal, financial, and other information; as well as provide legal expertise in the examination of the ATCs' principals and business structure to assist the Department in making informed decisions regarding ATC permitting.

Greenleaf Compassion Center (GCC) - Examination of GCC principals and business structure was initiated on December 15, 2011. Examination was completed on April 16, 2012. GCC was issued an ATC permit upon review and approval of the examination and attaining full regulatory compliance.

Compassionate Care Foundation (CCF) - Examination of CCF principals was initiated on February 13, 2012. Examination was completed on March 18, 2013. CCF was issued an ATC permit upon review and approval of the examination and attaining full regulatory compliance.

Garden State Dispensary (GSD) - Examination of GSD principals was initiated on September 4, 2012. Examination was completed on April 24, 2013. GSD was issued an ATC permit upon review and approval of the examination and attaining full regulatory compliance.

Breakwater ATC (Breakwater) - Examination of Breakwater principals was initiated on August 24, 2012. Examination was completed on December 13, 2013. Breakwater was issued an ATC permit upon review and approval of the examination and attaining full regulatory compliance.

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Compassionate Science ATC (CSATC) - The examination of CSATC principals, corporate structure, and funding source was initiated on February 12, 2013. Examination was completed on June 3, 2015. CSATC was issued an ATC permit upon review and approval of the examination and attaining full regulatory compliance.

Foundation Harmony (Harmony) - The examination of Harmony principals, corporate structure, and funding source was initiated on December 2, 2014 and is ongoing.

Examination timeframes are impacted by a number of factors including the complexity of the ATC business structure, their contractual agreements and their responsiveness to requests for information.

Patients/Caregiver Registry

The MMP developed an electronic patient and caregiver registration and payment process (the registry). The registry is an encrypted, public web application that provides end-to-end security of personal, medical and financial information of the applicant. This registry opened on August 9, 2012. Since the registry opened, 12,514 qualifying patients and 1,030 caregivers have been registered with the program. From January 1, 2016 through December 31, 2016, 5,060 qualifying patients and 315 caregivers registered with the program. The MMP has issued identification cards to 11,617 qualifying applicants completing the registration process. Additionally, all authorized debilitating illnesses are represented in the present patient population.

The patient and caregiver registration fee is \$200.00 for two years. Patients and caregivers that receive New Jersey Medicaid, Supplemental Nutrition Assistance Program (SNAP) benefits, New Jersey Temporary Disability Insurance benefits, Supplemental Security Income (SSI) benefits or Social Security Disability (SSD) benefits, receive a reduced registration fee of \$20.00. Approximately 45 percent of registered patients and caregivers receive the reduced application fee of \$20.00.

Physician Registry

Since the inception of the program, 529 physicians have registered with the program; of those physicians registered, 426 are active, 91 requested to be inactivated, and 12 were disapproved. From January 1, 2016 through December 31, 2016, 77 physicians registered with the program, 64 are active, 8 are inactivated, and 5 were disapproved. Of active physicians, 73 percent are currently

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authorizing patients for the program. All registered physicians are listed on the MMP website. Patients may ask their primary physician to register with the MMP or they may locate a participating physician on the website by county and/or medical specialty.

Participating physicians must hold an active New Jersey medical license in good standing issued by the NJ Board of Medical Examiners, possess an active controlled dangerous substances registration issued by the NJ Division of Consumer Affairs that is not subject to limitation, and practice within the State of New Jersey.

Outreach & Communication

The MMP developed a Customer Service Unit (CSU) to provide program information for physicians, patients, caregivers, ATCs and the public. Through December 31, 2016, CSU had responded to 47,463 public inquiries via telephone and e-mail. The CSU also assists patients and caregivers through the registration process.

The MMP communicates with ATCs in the examination process to facilitate the review of submissions. Additionally, the MMP communicates daily with operational ATCs to monitor activity, obtain status reports, and resolve any programmatic issues to ensure compliance with the Act and applicable regulations.

Education

The MMP has partnered with the New Jersey Board of Medical Examiners, the Medical Society of New Jersey, and the Drug Policy Alliance to provide an electronic library of scholarly articles and research materials, which are available on the MMP website.

The MMP has developed a Medicinal Marijuana Strain Library available to registered physicians and patients through the MMP registry. The library contains laboratory testing results of available strains of medicinal marijuana cultivated by the ATCs. As of December 31, 2016, there were 97 distinct strains tested which are posted on the library site. The library is designed to assist physicians and patients in making informed decisions regarding medicinal marijuana use.

Marijuana Testing

The MMP worked with several State agencies to develop marijuana sampling and testing protocols that ensure compliance with labeling standards and the quality of the product. Furthermore, the Department's Public Health Environmental

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Laboratory (PHEL) established additional, scientific protocols for product sampling and testing.

The PHEL worked with the Department of Agriculture to develop protocols related to testing for molds and pesticides. The MMP sampling and testing process was developed after researching marijuana testing protocols in the United States, Canada, and Europe. Product testing is necessary to establish cannabinoid profiles and screen the product for mold and other contaminants that can be dangerous for patients with compromised immune systems. The PHEL has developed a testing protocol for the detection of pesticides. Additionally, ATCs have provided the MMP with certification that no chemical pesticides are used in the cultivation of medicinal marijuana.

As of December 31, 2016, the MMP has conducted laboratory testing on 97 distinct strains of medicinal marijuana cultivated by operating ATCs.

Medical Review Panel

The table below lists the confirmed Medical Review Panel members, their specialty area, and requirements as per the rules.

Table 2: Medical Review Panel

Panel Member	Specialty	Rule Requirement
Stewart A. Berkowitz, MD	President, New Jersey State Board of Medical Examiners	President, New Jersey State Board of Medical Examiners
Alex Bekker, MD, PhD Chairperson	Anesthesiology	Pain & symptom management expertise/Physician
Petros Levounis, MD, MA	Psychiatry Addiction Medicine	Pain & symptom management expertise/Physician
Cheryl Kennedy, MD Vice Chairperson	Psychiatrist Addiction Medicine	Pain & symptom management expertise/Physician
Jessica Ann Scerbo, MD	Pediatric, Hematology & Oncology	Physician
Mary L. Johansen, PhD	Nursing	Non-physician
Mary M. Bridgeman, Pharm D.	Pharmacist	Non-physician
Stephanie Zarus, Pharm D.	Pain Management	Non-physician

Additional Debilitating Medical Conditions Process

The first Medical Review Panel meeting was held on May 25, 2016. During this meeting the Medical Review Panel Chairperson and Vice Chairperson were

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elected, the Medical Review Panel bylaws were approved and the panel received public comment from attendees.

From August 1, 2016 to August 31, 2016 the Department accepted petitions for additional debilitating medical conditions. At the close of this period the Department received sixty-eight (68) petitions.

A DOH review of the received petitions determined that forty-five (45) met the qualifications of the MMP Rules and Regulations and would be forwarded to the Medical Review Panel for review. Eighteen (18) did not meet the requirements and were returned to the petitioners. Five (5) petitions that were submitted for Post-Traumatic Stress Disorder (PTSD) were returned to the petitioners because on September 14, 2016, Governor Chris Christie signed N.J. Assembly Bill A-457 into law, allowing PTSD to be included as a debilitating medical condition under the “New Jersey Compassionate Use Medical Marijuana Act”.

In December 2016, the qualifying petitions were posted on the Department’s website and provided to the Medical Review Panel. The Panel will be holding public meetings in 2017 to consider each of those petitions and to make recommendations to the Commissioner of Health.

Regulatory Process

Manufacturing Standards

In March 2015, the Department provided standards to the ATCs for manufacturing lozenge, topical formulations and edible form products. To date, one ATC (Compassionate Science) has implemented the manufacturing standards and is currently dispensing a lozenge and a topical formulation.

Permitting Process

The Department and New Jersey Department of Law and Public Safety (LPS) established a permitting process to thoroughly review the financial and personal backgrounds of the principals associated with the ATCs. The permitting process is modeled after protocols and procedures for reviewing the background and finances of casino operators undertaken by the Division of Gaming Enforcement, within LPS. Additionally, the MMP has developed an:

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- Online registration process for patients, caregivers and ATC employees. Successful applicants are issued an identification card specific to their role within the program;
- Identification card system with various security features that mitigate counterfeiting and which can be validated by law enforcement through an online search; and
- ATC Monitoring Unit that conducts on-site inspections, monitors the ATCs by video in real time, and remotely accesses the ATC internal inventory management systems.

The DOH has collaborated with several State and private entities to implement the Act, including, but not limited to, LPS, including the Office of the Attorney General, the Boards of Medical Examiners and Pharmacy, and the Division of Gaming Enforcement; the Departments of Agriculture, Environmental Protection, Labor and Workforce Development, and Treasury; the Motor Vehicle Commission; Rutgers University; the University of Mississippi; the Drug Policy Alliance; the Medical Society of New Jersey; and the Coalition for Medical Marijuana New Jersey. Each has lent expertise to program implementation and operation.

Budget

The State Fiscal year 2017 (SFY17) MMP budget consists of an appropriation of \$1,607,000 and a carry forward from SFY16 of \$98,386 for a total overall budget of \$1,705,386. Revenue generated from January 1, 2016 to December 31, 2016 from the issuance of patient and caregiver identification cards and ATC permitting is \$881,358. This revenue is used to help offset the operating cost of the program.

Program Statistics

Patient Registry Applications

	<u>New in 2016</u>	<u>Total from Program Inception</u>
Patients Active	4,735	10,799
Patients Inactive	22	245
Patients Deceased	303	1,470
<u>Patients Disapproved</u>	<u>215</u>	<u>613</u>
Total Patient Applications	5,275	13,127
Qualifying Patients Registered*	5,060	12,514

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Caregiver Registry Applications

	<u>New in 2016</u>	<u>Total from Program Inception</u>
Caregivers Active	180	543
Caregivers Inactive	135	487
Caregivers Disapproved	0	0
Total Caregiver Applications	315	1,030

Primary Caregivers Registered* 315 1,030

Registry Identification Cards Revoked 0

*Approximately 45% of registered patients and caregivers qualified for and received the reduced application fee of \$20.00.

Physician Registry

	<u>New in 2016</u>	<u>Total from Program Inception</u>
Physicians Active*	64	426
Physicians Inactivated	8	91
Physicians Disapproved	5	12
Total Physician Activity	77	529

*Of the 426 active registered physicians, 309 or 73% are executing certifications for registered patients.

Alternative Treatment Center Examinations (Through December 31, 2016)

Initiated	6
Completed	5
Ongoing	1

Alternative Treatment Center Permits (Through December 31, 2016)

Issued	5
Full	5
Limited	0
Revoked	0

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Table 3:

Nature of the Patients' Qualifying Illness

(August 9, 2012 through December 31, 2016)

Debilitating Condition	Count of Patient Conditions	Percentage of Population
Glaucoma	309	1.77%
Inflammatory Bowel Disease	1,792	10.25%
Intractable Skeletal Spasticity	6,748	38.61%
Lateral Sclerosis	101	0.58%
Multiple Sclerosis	1,356	7.76%
Muscular Dystrophy	163	0.93%
*Post-Traumatic Stress Disorder (PTSD)	466	2.67%
Seizure Disorder	913	5.23%
Severe or Chronic Pain	4,177	23.90%
Terminal Cancer	1,152	6.59%
Terminal Illness	299	1.71%
Grand Total	**17,476	100.00%

* On September 14, 2016, N.J. Assembly Bill was signed into law by Governor Chris Christie, allowing PTSD to be included as a debilitating medical condition under the "New Jersey Compassionate Use Medical Marijuana Act".

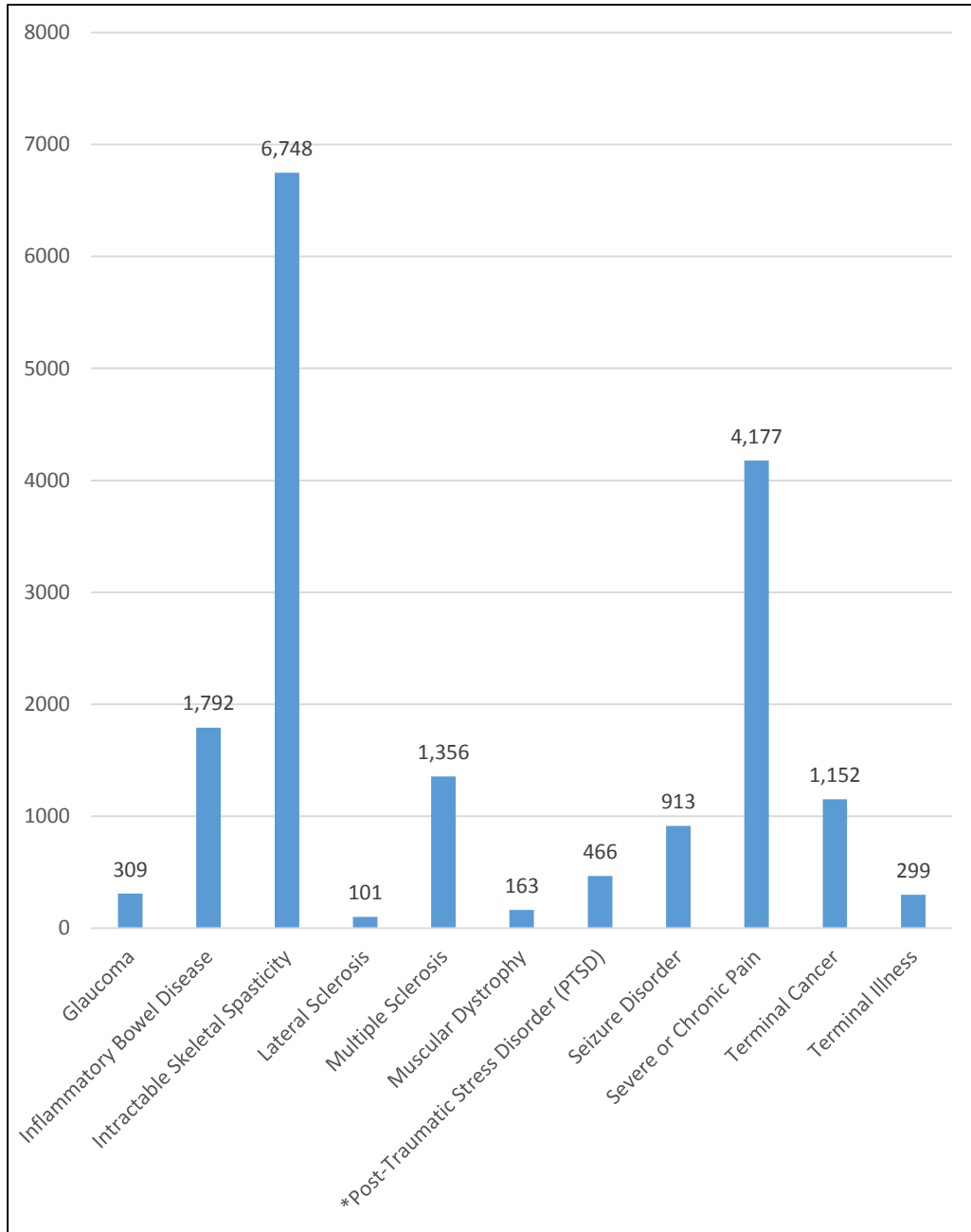
**Condition count is greater than patient total as some patients suffer from multiple qualifying illnesses.

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Figure 1:

Frequency of Condition

(August 9, 2012 through December 31, 2016)

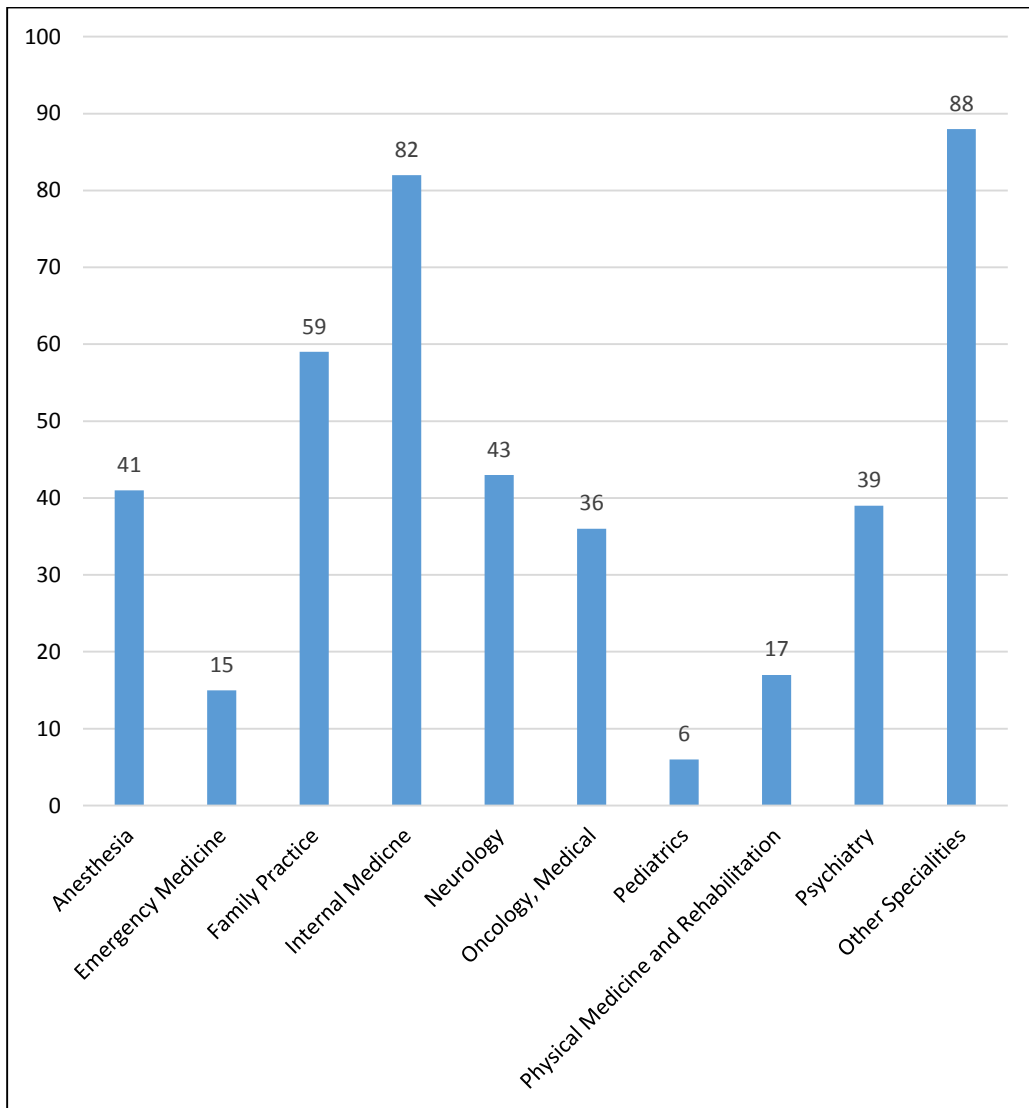


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Figure 2:

Active Registered Physicians by Specialty

(August 9, 2012 through December 31, 2016)



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Figure 1:

Caregiver Frequency by Patient Condition

(August 9, 2012 through December 31, 2016)

