Maryland Medical Cannabis Commission

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Annual Report FY2020

Our mission

... to provide a safe, effective and consumer-friendly medical cannabis program for qualifying patients.

Our vision

... a high quality, equitable and compliant medical cannabis program that serves as a nationwide model.

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A Message from the Executive Director



A Tribute to Fakiza Rahman

"This Fiscal Year 2020 Annual Report is dedicated to our friend and colleague Fakiza Rahman. Ms. Fakiza Rahman was the Maryland Medical Cannabis Commission's Director of Operations until she passed away on March 12, 2020, surrounded by her family and many friends after a nearly two year battle with cancer. Fakiza was the most hard-working, compassionate, and generous colleague, and the MMCC and the State of Maryland are forever changed for the better because of her efforts on behalf of seriously ill and injured

Marylanders. She cared immensely for the Maryland Medical Cannabis Program and for each of the patients who sought relief in it.

Fakiza started with the MMCC in April 2017 – the same week the patient registry opened – and was instrumental in building the Program from the ground up. Over the past three years, Fakiza helped tens of thousands of Marylanders register to obtain medical cannabis to treat severe and chronic pain, seizure disorders, cancer-associated pain and nausea, glaucoma, post-traumatic stress disorder, and many other life-threatening or serious medical conditions. Fakiza also administered the State's medical cannabis seed-to-sale tracking system (METRC) and agent registration system (Complia), and supervised nearly two dozen employees. She did everything at MMCC. If anyone – a Commission member or employee, patient, caregiver, provider, or licensee – had a question, Fakiza was the one we so often went to for an answer. Simply put, she was the best of us. The best coworker, manager, mentor, and friend.

Fakiza was also the embodiment of a selfless public servant. She gave everything she had to the MMCC and to the patients of Maryland; working nights and weekends, and always volunteering first whenever anyone needed assistance. Fakiza continued to assist patients while she was in the hospital fighting for her life. In her honor and with gratitude, we pay tribute to Fakiza Rahman."

Will Tilburg, JD, MPH Executive Director

About us

The Maryland Medical Cannabis Commission (MMCC) is an independent commission within the Maryland Department of Health. The MMCC oversees all licensing, registration, regulation development, inspection, and testing measures pertaining to the medical cannabis program, and provides program information to patients, providers, licensees, and other stakeholders. The MMCC is devoted to performing all its regulatory activities in accordance with our Mission and Vision, with patient safety at the forefront of everything we do.

Who we are

The MMCC is comprised of 13 Commissioners and 52 full-time staff members.

Commissioners are responsible for governing the Maryland Medical Cannabis Program. They oversee the regulatory, administrative, educational and research, and reporting activities of the MMCC. All major programmatic decisions must be voted on and approved by the full Commission during a public meeting. To ensure that adequate time for deliberation and subject matter expertise is given to all decisions, there are five standing committees upon which Commission members serve.

Executive Committee

Chair Brian Lopez
Sandy Washington
Liz Hines
Tiffany Randolph
Nancy Rosen-Cohen

Compliance Committee

Chair Phil Cogan Obi Onyewu Scott Welsh

Finance & Budget Committee

Chair Obi Onyewu Konrad Dawson Phil Cogan

Policy Committee

Chair Tiffany Randolph Charles LoDico Liz Hines Scott Welsh Megan Dingus

Research & Education Committee

Chair Charles LoDico Jinlene Chan Ehsan Abdeshahian Konrad Dawson

Commission staff support seven major departments – Enforcement and Compliance, Communications, Finance, Information Technology, Policy and Government Affairs, Scientific Support, and Quality Assurance. These departments provide day-to-day support for MMCC operations, and act as the liaison between stakeholders and Commissioners.

- Executive Director William Tilburg, JD, MPH
- Deputy Director Lori M. Dodson, MS, MT(ASCP)

A Message from the Chair



behalf of the Maryland Medi-Commis-Cannabis sion (MMCC) and with my fellow commissioners, it is my honor and pleasure to report on our substantial accomplishments during FY2020, as well as the changes made to further our mission.

Our fundamental motiva-

tion at the Commission is to ensure medical cannabis is available to qualifying patients in a safe and effective manner. The Commission carried out a series of activities during FY2020 (July 1, 2019 to June 30, 2020) that address priority issues focusing on our mission:

- Quality Assurance Patient application turnaround time was reduced from 30 days to 10 days and our IT infrastructure has been greatly enhanced to improve usability and reduce system down time.
- Enforcement and Compliance 19 pre-approved applicants received full licensure across the State to grow, process, or dispense medical cannabis.
- Policy and Government Affairs Created and established regulations to safely manufacture and dispense edible cannabis products, as well as developed advertising guidelines for our licensees.
- Patient and Provider Growth Our patient population nearly doubled - growing from 54,939 to 102,459 patients during FY2020 - and the number of registered medical providers certifying patients increased from 1,468 to 1,894 certified providers.
- Education and Training The Commission developed a standardized education curriculum for certifying providers and dispensary agents.

In June 2019, the Commission launched its application process to award four additional grower and 10 additional processor licenses. Despite some initial technical difficulties with the technology, the application process produced more than 200 applications with the vast majority (approximately 90 percent) being submitted by minority and women-owned businesses.

The medical cannabis industry in Maryland is robust and we look forward to the coming year. As we continue to strengthen every aspect of our program, we will remain focused on the following goals:

- Continued and improved diversity in ownership We look forward to announcing the pre-approvals of our license application process and finding new and creative solutions for providing minority ownership amongst our licensees.
- Continued Growth The Commission awarded a procurement in July 2020 to conduct a market analysis on the medical cannabis industry in Maryland. The analysis will assess current capacity and future needs.
- Standardized and consistent regulatory enforcement and compliance - Consistency across the State is important to all of our stakeholders.
- Expanded Research and Education Explore research opportunities with our institutions and engage with our stakeholders in order to provide educational opportunities to all of our stakeholders

We look forward to another year of continued growth and complex policy and legislative issues. We expect a year of new challenges and the opportunity to continue making Maryland's Medical Cannabis Program the best in the country.

> Brian Lopez Commission Chair

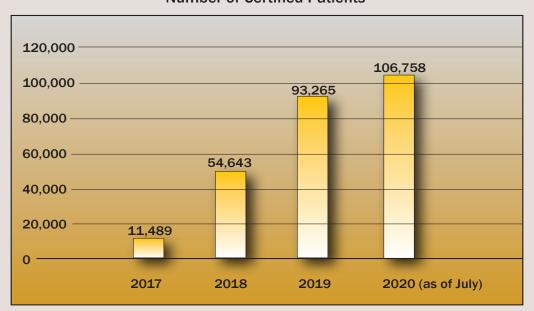
Patient Population

Medical cannabis patients are central to all aspects of the Maryland Medical Cannabis Program (the Program). The number of patients continues to grow as a steadily increasing number of individuals seek the therapeutic benefits of medical cannabis.

As of July 2020, the MMCC had registered 106,758 patients. Of that total, 183 were minor patients, and 520 were hospice patients. In addition, as of July 2020, the MMCC had registered 8,079 caregivers to assist patients with the administration of medical cannabis.

The MMCC receives over 200 applications per day from patients seeking to register with the Program. The average amount of time to process these registrations has decreased from 30+ days to 10 days, even in the wake of the COVID-19 pandemic. Central to this decrease in processing time are our Quality Assurance staff, who work tirelessly to ensure that all patient requests and questions are answered in a timely manner. The recently established MMCC call center has also greatly helped to improve service to patients, by connecting them directly with health and other experts. The call center receives 200 – 250 calls per day.

Number of Certified Patients



Who is eligible to become a medical cannabis patient in Maryland?

Any individual living in Maryland whose certifying medical cannabis provider recommends medical cannabis as a treatment option for a qualifying medical condition is eligible.

What are medical cannabis caregivers?

Caregivers are registered individuals, aged 21 or older, who are permitted to purchase medical cannabis on behalf of a patient, and assist with that patient's administration of medical cannabis. A registered adult-patient may designate up to two caregivers. All registered minor-patients must have a caregiver who is the minor-patient's parent(s) or legal guardian(s). At most, a minor-patient may have four caregivers: two of whom are parents or legal guardians, and two of whom are additional designated adults.

Who is Eligible to Provide a Certification for Medical Cannabis?

A health care provider licensed and in good standing in Maryland from any of the following provider categories may register with MMCC to become a certifying provider: physicians, dentists, podiatrists, certified nurse practitioners, certified nurse midwives, and beginning October 1, 2020, physician assistants.

The MMCC currently has 1,894 certifying providers located throughout the State who are registered to provide patient certifications.

What is a Qualifying Medical Condition?

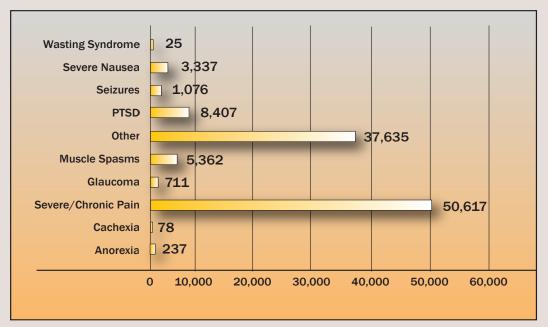
A certifying provider may recommend medical cannabis as a treatment option for a patient experiencing a chronic or debilitating disease or medical condition that results in:

- Being admitted into hospice or receiving palliative care,
- · Cachexia,
- Anorexia,
- Wasting syndrome,
- · Severe or chronic pain,
- Severe nausea,
- · Seizures.
- Severe or persistent muscle spasms,
- Glaucoma,

- Post-traumatic stress disorder (PTSD), or
- Another chronic medical condition which is severe and for which other treatments have been ineffective – also referred to as the "other" category in the chart below.

As demonstrated below, severe or chronic pain is the most common qualifying condition affecting our patient population, a number of whom are seeking an alternative to opioids and other prescription medication.

Patient Numbers by Condition



Program at a Glance

The Maryland Medical Cannabis Program became operational on December 1, 2017. In its nearly three years of operation, the Program has experienced immense growth in all areas, from patient population to dispensary sales to number of the MMCC staff members.

As of July 1, 2020, the MMCC has licensed:

- 17 medical cannabis growers, who are responsible for cultivating the medical cannabis.
- 17 medical cannabis processors, who are responsible for processing the raw medical cannabis flower into various products, such as tinctures and oils.
- 91 medical cannabis dispensaries, who are responsible for the sale of medical cannabis to patients and caregivers.

FY2020 Average Price Per Gram

The average price per gram has fallen significantly, since a high of \$15.97 in January of 2018. During the past 2 ½ year sales period, the average price per gram has largely leveled out, remaining relatively stable throughout 2019 and 2020.

Program

Average Price per Gram



Monthly Dispensary Sales



Year-to-Year Sales - Medical Only



Program Diversity

The MMCC is committed to promoting diversity and the participation of diverse groups within the medical cannabis industry, including small, minority, and women-owned businesses. The MMCC's goal is for the medical cannabis program to reflect the broad race, gender, ethnicity, and socioeconomic diversity of the State of Maryland.

To assist in these efforts, the MMCC tracks program diversity through the Annual Minority Disclosure forms that each licensee must submit by June 30 each year.

On October 1, 2020, the MMCC awarded three grower license preapprovals and eight processor license preapprovals. Majority ownership (e.g. 51% or more) of each newly preapproved entity is held by disadvantaged minority and women owners. As a result, six out of 21 licensed/preapproved growers and 14 out of 26 licensed/preapproved processors are majority-owned by minority and women owners.

Licensed and Pre-Approved Growers

As of July 1, 2020

12 out of 18 have women and/or minority owners

3 out of 18 have >50% ownership interest held by women and/or minorities

Licensed and Pre-Approved ProcessorsAs of July 1, 2020

11 out of 18 have women and/or minority owners

6 out of 18 have >50% ownership interest held by women and/or minorities

Licensed Medical Cannabis DispensariesAs of July 1, 2020

61 out of 91 have women and/or minority owners

36 out of 91 have >50% ownership interest held by women and/or minorities

Diversity within the MMCC

Commission MembersAs of July 1, 2020

10 out of 13 Commission members are women and/or minorities

MMCC Staff Overall As of July 1, 2020

41 out of 52 staff members are women and/or minorities

MMCC Staff Leadership As of July 1, 2020

8 out of 10 staff members in senior leadership roles are women and/or minorities

Compliance

The MMCC's compliance efforts are critical to ensuring product and patient safety and form the backbone of the Maryland Medical Cannabis Program. The integrity of the Program depends on the strength of its compliance operations, which are handled by two departments:

- The Bureau of Enforcement and Compliance (BEC), which is responsible for overseeing the inspection and discipline of licensed growers and dispensaries to ensure conformity with Maryland's medical cannabis statutes and regulations, and
- Scientific Support (SS), which is responsible for overseeing the
 inspection and discipline, as well as the standards of care and
 testing protocols for licensed processors and registered independent testing laboratories to ensure conformity with Maryland's
 medical cannabis statutes and regulations.

These two departments are responsible for ensuring that all medical cannabis licensees comply with product safety and quality assurance requirements. The MMCC staff conduct pre-licensing inspections, random unannounced compliance inspections, and inspections in response to product safety or quality complaints.

The chart below details the inspection activity for FY2020.

Inspection Activity	SS - FY2020	BEC - FY2020
Routine	22	438
Complaint	1	80
METRC Audits	4	34
Virtual Audits*	22	15
Full Licensing	0	6

^{*} As a result of the COVID-19 pandemic

New Compliance Enhancements and Guidance

The MMCC is foremost a regulatory body charged with protecting public health and safety. As such, the MMCC continually works to find new and innovative ways to enhance its compliance activities.

Technical Authority for Independent Testing Laboratories

With the assistance of a Laboratory Testing Workgroup, the MMCC has established a technical authority reference guide for independent testing laboratories to follow when analyzing medical cannabis. Testing of medical cannabis for safety and potency is essential to minimizing the risk of patient exposure to harmful microbials, heavy metals and other contaminants, as well as quantifying the cannabinoid profiles and potency to assist patients and providers with product selection and dosing. This reference guide will help improve and standardize the quality and accuracy of testing.

Inspection and Reporting

MMCC has improved and streamlined the inspection and reporting processes to achieve higher quality results and to continue to ensure patient safety. Further, the MMCC recently promulgated regulatory changes to enhance its inspections and enforcement capability. The regulations strengthen video surveillance of licensed grower, processor, and dispensary premises; establish mandatory reporting whenever a licensee finds evidence of theft or diversion; and require a licensee to enter timely and accurate data into METRC to better track the licensee's stock of medical cannabis.

Budget

The MMCC's operating budget comes from its own special fund. This means the Program is 100% self-funded, and receives no money from taxpayer dollars or the State's General Fund. Rather, all funding for MMCC program operations are from dollars generated by the Program itself. As shown in the chart below, the MMCC's main source of funding is from licensing and patient ID card fees.

	FY2017	FY2018	FY2019	FY2020
Licensing Fees	\$4,170,700	\$2,633,400	\$5,901,400	\$5,898,835
Agent ID Cards	\$9,800	\$389,830	\$486,044	\$756,000
Patient ID Cards	\$53,500	\$452,800	\$3,796,650	\$4,045,450
Interest/Fines	\$0	\$32,464	\$187,383	\$167,339
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Total Revenue	\$4,234,000	\$3,508,494	\$10,371,437	\$10,867,623
Total Revenue	\$4,234,000	\$3,508,494	\$10,371,437	\$10,867,623
Total Revenue Personnel Cost	\$4,234,000 \$1,351,280	\$3,508,494 \$1,809,155	\$10,371,437 \$2,981,972	\$10,867,623 \$4,015,151

COVID-19 Emergency Measures

Along with the rest of the State, the MMCC was propelled into action in response to the COVID-19 pandemic. Since March 2020, the MMCC has made significant programmatic adjustments to ensure patients continued access to safe and effective medical cannabis. This includes issuing 10 COVID-related bulletins that recommended State and CDC precautionary safety measures, reduced patient-employee interactions, and authorized telehealth measures.

Since March, the MMCC has increased access to medical cannabis and made access safer by authorizing dispensaries to dispense cannabis via drive-through and curbside pickup, expanding delivery of medical cannabis to facilities and residences where patients and caregivers reside, allowing telehealth visits between certifying providers and patients, and suspending patient and caregiver attestation and signature requirements. Furthermore, the MMCC implemented licensee social distancing requirements and clarified operational best practices at licensed facilities during the COVID-19 pandemic to ensure that potential for exposure is as limited as possible.

Despite the unprecedented and rapidly evolving landscape of COVID-19, the MMCC operations remain largely uninterrupted. This outcome can be attributed in large measure to the immense work by the MMCC's staff, who remain devoted to ensuring continuity of programmatic operations, in conjunction with the hard work and cooperation of medical cannabis licensees.

Given the success of certain COVID-19 measures, the MMCC approved regulations authorizing drive-through dispensing to remain in place. "Drive-through dispensing" is a method of dispensing medical cannabis through a window or other opening in the exterior wall of a dispensary. This type of dispensing enables a registered dispensary agent to provide services to a qualifying patient or registered caregiver who drives a vehicle to the dispensary without a registered dispensary agent leaving the dispensary service area or qualifying patient or registered caregiver leaving his or her vehicle.

The MMCC is engaged in communications with medical cannabis licensees, patients, and other interested stakeholders on the potential

merits of continuing a number of the MMCC's COVID-19 emergency measures. Licensees, patients, and caregivers alike have reaped benefits from some of the temporary measures currently in place, such as telehealth visits and medical cannabis deliveries to patient and caregiver residences and facilities, among others, and expressed a desire for these activities to continue.

Policy

The Maryland Medical Cannabis Program has benefited from a number of important legislative and regulatory milestones during the past year. As illustrated below, the MMCC has or is in the process of implementing notable policy changes to continue improving the medical cannabis program, and to ensure safe, high-quality medicine is available for the patients we serve.

Legislative Accomplishments

The MMCC proudly supported the following legislation championed by our legislative partners:

Administration of Medical Cannabis on School Grounds

Groundbreaking legislation was enacted in which Maryland became one of a handful of states in the U.S. to authorize school personnel to administer medical cannabis to qualifying students on school property, at school-sponsored activities, and on a school bus in accordance with guidelines developed by the Maryland State Department of Education and the MMCC, starting in 2021. Furthermore, effective June 1, 2020, caregivers of students who are qualifying medical cannabis patients may administer medical cannabis to students on school property, during school - sponsored activities, and on a school bus. A parent or guardian of a minor qualified patient may designate up to two additional adults to serve as caregivers, allowing a minor qualified patient to have up to four caregivers.

Prior to enactment, caregivers of students who are qualifying medical cannabis patients had to remove the student from school property in order to administer their medicine, causing an often untenable disruption to the student's class time. By facilitating the student's continuity of care and access to education, this law ensures that medical cannabis patients will be able to attend school and participate in school activities while continuing their treatment which cannot reasonably be accomplished outside of school hours. See House Bill 617/Senate Bill 604 (2020) sponsored by Delegates Steve Johnson, Nicholaus Kipke and Mary Ann Lisanti and Senator Brian Feldman, respectively.

Certifying Providers

Beginning October 2020, physician assistants will be permitted to register with the MMCC as certifying providers. This will help increase patient access to certifying providers, many of whom are presently clustered in areas of the State such as Baltimore City and Montgomery County. See House Bill 378/Senate Bill 304 (2020) sponsored by Delegate Nicholaus Kipke and Senator Chris West, respectively.

The Fakiza Rahman Act - Compassionate Use Fund

This legislation provides a funding mechanism for the Compassionate Use Fund in order to make medical cannabis available at a reduced cost to Maryland Medicaid recipients and veterans. The bill was named in honor of Fakiza Rahman, the MMCC's former Director of Operations who passed away in March 2020 after a spirited battle with cancer. Ms. Fakiza Rahman's impressive work at the MMCC was influential in successfully launching the medical cannabis program, and her indelible legacy will shape its trajectory for many years to come.

Since the inception of the Maryland Medical Cannabis Program, many patients, caregivers, providers, and other constituencies have voiced concerns over the cost of medical cannabis for low-income and other vulnerable populations. This legislation is a step toward addressing and ameliorating those concerns.

The MMCC is required to establish the program by:

- Setting a structure to assess fees on licensed growers, processors, and dispensaries to provide funding for reduced-cost cannabis through the Compassionate Use Fund.
- Establishing a procedure to collect fees on licensed growers, processors, and dispensaries.
- Reimbursing licensed dispensaries for the reduced-cost medical cannabis.

The MMCC expects the Fund to be operational by mid-2021. See House Bill 870 (2020) sponsored by Delegate Joseline Pena-Melnyk.

Regulatory Progress

Clinical Director

Effective November 1, 2020, all licensed dispensaries must appoint a Clinical Director with specialized training in medical cannabis scientific research, risks and benefits to be available to any patient onsite or electronically. The Clinical Director will be able to help patients and caregivers better understand potential drug-to-drug interactions, including interactions with alcohol, prescription drugs, non-prescription drugs, and supplements; possible side effects or contraindications of medical cannabis use; the potential for differing strengths and effects of medical cannabis strains; and different methods, forms, and routes of medical cannabis administration.

Patient ID Card Fee Waiver

Given that medical cannabis is not currently covered by insurance, patients must pay out-of-pocket, which represents a financial hardship for many patients and their families. In order to help alleviate some of the cost burden and help increase access, the MMCC has waived the \$50 patient ID card fee for Maryland Medical Assistance Program recipients and Veteran's Affairs Health Care System enrollees. For existing patients, the fee will be waived upon renewal.

Edible Medical Cannabis Products

The highly anticipated implementation of regulations allowing for the manufacture and sale of edible medical cannabis products is expected to take place in Fall/Winter 2020.

Over an 18-month period, the MMCC held workshops and conducted outreach to a broad group of stakeholders, including legal, medical, public health, laboratory, and industry experts, to establish a regulatory framework for the oversight of the processing and distribution of edible cannabis products. The result is one of the most comprehensive regulatory frameworks for edible medical cannabis products in the country.

Ownership and Control of Medical Cannabis Licenses

An individual or entity may only have an ownership interest in, or control over, one grower license, one processor license, and up to four dispensary licenses. In order to ensure the MMCC can adequately regulate licensees and remain abreast of any changes in ownership and control of licenses, the MMCC implemented the following regulatory changes, which took effect on May 8, 2020:

- The restriction on the sale or transfer of ownership of a license has been extended from two to three years.
- All licensees must submit an annual disclosure of organization, ownership, and control to the MMCC by July 1 of each year, or upon request.
- Commission approval is now required for a transfer of any ownership interest to an individual or in a privately held entity, and for a transfer of five perent or more ownership interest in publicly held entity.
- Commission approval is now required for a transfer of control of a license to a third party (i.e. a management company).

Oversight of Advertising Restrictions

The MMCC has increased oversight of medical cannabis advertising as a result of legislation enacted by the Maryland General Assembly in 2019 that imposed specific restrictions on medical cannabis

advertising. The new law contains a number of advertising restrictions, that include safeguarding against false or misleading advertising and requiring that therapeutic or medical claims associated with medical cannabis must be supported by substantial clinical evidence or data and include information on the most significant side effects or risks associated with use.

The MMCC has promulgated regulations and provided guidance to licensees to help clarify the restrictions on advertising, and to guide compliance. The MMCC accepts complaints and reports of advertisement violations, and will review and investigate, if necessary. Furthermore, the MMCC accepts proposed advertising materials from licensees who wish to receive feedback from MMCC staff or a formal advisory opinion from the full Commission as to whether a proposed advertisement complies with State law.

Dispensary Agent Training

The MMCC developed a training curriculum as on online resource to assist dispensary agents with understanding and complying with medical cannabis sales laws. This training is expected to be available on the MMCC website in FY2021.

Patient Education Materials

The MMCC developed training materials to address frequently-asked questions by patients and providers. The materials address: 1) MMCC and Program overview; 2) How to become a medical cannabis patient; 3) Laboratory testing and medical cannabis products; 4) Bureau of Enforcement and Compliance responsibilities; and 5) Medical cannabis advertising requirements for licensees, certifying providers and third-party vendors. The materials will be made available via our website and by request in hardcopy.



Moving Forward Together

Looking to the future, the MMCC has many exciting initiatives planned and currently in progress for FY2021. Such initiatives include the processing and distribution of edible medical cannabis products, measures to help reduce and streamline administrative processes for medical cannabis businesses, and the issuance of a grant for the data collection and evaluation of health outcomes of medical cannabis patients. The MMCC also plans to standardize Program best practices across jurisdictions through collaboration with regulators across the country.

In light of continued programmatic growth, and the potential for legalization of adult-use cannabis on the horizon, the MMCC awarded two competitive procurements to analyze and report on: 1) the health and public safety effects of legalizing adult-use cannabis, and the impact legalization may have on the Program; and 2) the current and future size of the Program, and the economic impact of legalizing adult-use cannabis in Maryland. These reports will assist the MMCC in analyzing Program strengths and gaps, refining a regulatory framework that will enhance public health goals, minimizing the opportunity for diversion to the illicit market, and making other recommendations for overall programmatic improvement.

The MMCC greatly appreciates the strong commitment demonstrated by the Maryland General Assembly, industry partners, and the community through ongoing efforts to support us in providing a high-quality, accessible medical cannabis program in Maryland. We hope that this FY2020 Annual Report illustrates the success of the Maryland Medical Cannabis Program to date, and emboldens us to move forward with continued progress on behalf of the patients we serve.

Operating Principles

- . . .Transparency
- ... Communication
- . . . Compliance and Quality
- ... Education
- ... Equity

Maryland Medical Cannabis Commission

849 International Drive, 4th Floor, Linthicum, MD 21090

410-487-8100 mmcc.maryland.gov