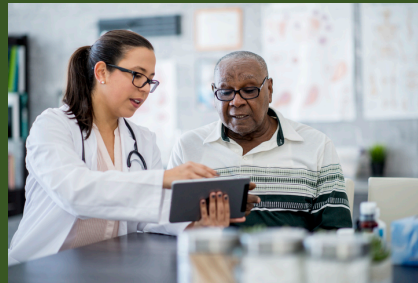


Missouri Medical Marijuana Regulatory Program

Annual Report to the Governor Program Year 2019



Missouri Department of Health and Senior Services

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Executive Summary

Background

On November 6, 2018, 65 percent of Missouri voters passed Amendment 2 into law, legalizing the medical use of marijuana for qualifying Missouri patients.

Article XIV of the Missouri Constitution became effective December 6, 2018, and granted the Missouri Department of Health and Senior Services (DHSS) the authority and responsibility to create a well-regulated program to ensure the availability of, and safe access to, medical marijuana. Thus, the Section for Medical Marijuana Regulation (SMMR) was created within DHSS to oversee the Medical Marijuana Regulatory Program (MMRP). Per Article XIV, DHSS is required to submit annually a report to the Governor detailing the efficient discharge of its duties. Reported activities, herein, are based on the MMRP program year (PY) of December 6, 2018, through December 5, 2019, which may be referred to as PY19.

Article XIV only authorizes the medical use of marijuana. Medical marijuana refers to any strain of cannabis with a tetrahydrocannabinol content of greater than 0.3% on a dry weight basis. The provisions for medical use of marijuana in Article XIV specifically allows:

- Missouri licensed physicians the right to discuss medical marijuana with their patients.
- Physicians the right to recommend marijuana for medical purposes to patients with qualifying medical conditions.
- Patients the right to discuss medical marijuana with their physician and to use marijuana under the supervision of their physician.

Key Achievements

In PY19, DHSS successfully navigated program implementation through the solicitation of high quality services in organizational consultation, information technology (IT) system development for patient and facility registrations and seed-to-sale tracking, and blind application scoring services for award of facility licenses. Additionally, DHSS was strategic in staffing the SMMR with highly skilled and motivated individuals to ensure constitutional deadlines could be met with minimal staff in early stages of program development. Lastly, DHSS devoted substantial time in regulatory research to identify crucial trends, successes, and challenges in other regulated marijuana states and invested considerable time in stakeholder engagement to leverage expertise and develop a comprehensive understanding of the public's expectations.

DHSS achieved every milestone within the timeframes specified by Article XIV for PY19. Future program success will be achieved through continuous quality improvement guided by evidence-based practices; collaborating with public and private entities; and responsive and timely communication with patients, facilities, and other stakeholders. Furthermore, DHSS will ensure that staff training and public education materials are consistently updated and administered to create a program of integrity, transparency, and accountability that meets high standards of safety and quality.

Introduction

This report is an accounting to the Governor regarding the efficient discharge of the following DHSS responsibilities as granted in Article XIV, Section 1 of the Missouri Constitution and encompasses those activities that occurred during PY19:

- Promulgate rules;
- Establish a system to numerically score facility applicants;
- Develop forms, certificates, licenses, ID cards and applications;
- Charge fees for licenses and certifications issued pursuant to Section 1;
- Grant or refuse facility licenses and certifications;
- Establish seed to sale tracking; and
- Suspend, fine, restrict, or revoke licenses and certifications.

Constitutional Deadlines

Article XIV established implementation deadlines for accepting pre-filed facility applications and fees; creating, publishing, and accepting all application types; and issuing identification cards, licenses, and certifications. To meet the constitutional requirements, the SMMR had to: (1) Establish a method for accepting pre-filed application fees, (2) Contract for services to develop an online application registration, (3) Post sample applications, forms, and instructions for facilities, (4) Begin accepting patient applications and issuing patient identification cards, (5) Launch a facility application period and contract with a vendor to score applications, (6) Review applications and submit them to the blind scoring vendor, and (7) Inform the public of expected facility license issuance dates.

Through timely procurement of services and identification of administrative efficiencies, all constitutionally specified dates, as noted in Figure 1, were successfully met.

Figure 1: Constitutional Deadlines

- Within 30 days (January 5, 2019), DHSS shall begin accepting pre-file license applications fees.
- Within 180 days (June 4, 2019), DHSS shall make available to the public all application forms and instructions for qualifying patients, patient cultivators, and caregivers.
- Within 180 days (June 4, 2019), DHSS shall make available to the public all application forms and instructions for medical marijuana cultivation, testing, dispensary, and medical marijuana-infused products manufacturing facilities.
- Within 210 days (July 4, 2019), DHSS shall begin accepting qualifying patient, patient cultivation and caregiver applications.
- Within 240 days (August 3, 2019), DHSS shall begin accepting medical marijuana cultivation, testing, dispensary, and medical marijuana-infused products manufacturing facilities, seed-to-sale tracking systems, and transportation of marijuana applications.

Mission and Vision

Charged with administering the MMRP, DHSS aligned its priorities and goals with the needs of the new program to ensure efficient and successful implementation of the MMRP. This is evident in the DHSS 2019 Strategic Priorities Placemat, which is a comprehensive and methodical design identifying initiatives and themes targeted at accomplishing the Department's overarching aspirations. One initiative focuses directly on the MMRP and asserts DHSS will: "Ensure medical marijuana milestones are being identified and completed." This initiative serves to support a DHSS-wide goal to "Enhance access to care," and ultimately, to "protect health and keep people in Missouri safe."

The MMRP mission and vision were developed with consideration of both DHSS goals and the will of the voters. Three strategic priorities and definitive goals were identified as necessary to achieve the mission. Collectively, these priorities and goals established the foundation for implementing Missouri's standards for the MMRP.

Mission

To administer Missouri's Medical Marijuana Regulatory Program in alignment with the provisions of Article XIV of the Constitution, as determined by the will of the citizens of Missouri.

Strategic Priorities

1. Make medical marijuana accessible for qualifying patients in Missouri;
2. Uphold safety and quality standards for medical marijuana; and
3. Regulate the medical marijuana industry to comply with Missouri law and keep communities safe.

Goals

1. Fulfill the will of the voters by ensuring all required deadlines are met while protecting the constitution;
2. Learn from other states that have gone through this process before, while keeping Missouri's unique characteristics in mind.
3. Create a level playing field by enforcing all regulatory requirements in a firm, transparent, and consistent manner.

Supporting Value Statements:

1. We are committed to being transparent in our processes and accountable for our decisions that impact those we serve.
2. We believe that collaboration with partners leads to administrative efficiencies and has a positive impact on service delivery.
3. We believe that research and analysis informs our practices and leads to the most effective high quality programs.
4. We strive to provide the highest level of quality in the delivery of our services.

Vision Statement

A program that provides safe and secure access to medical marijuana for qualifying Missouri patients through consistent regulation, enforcement, and education.

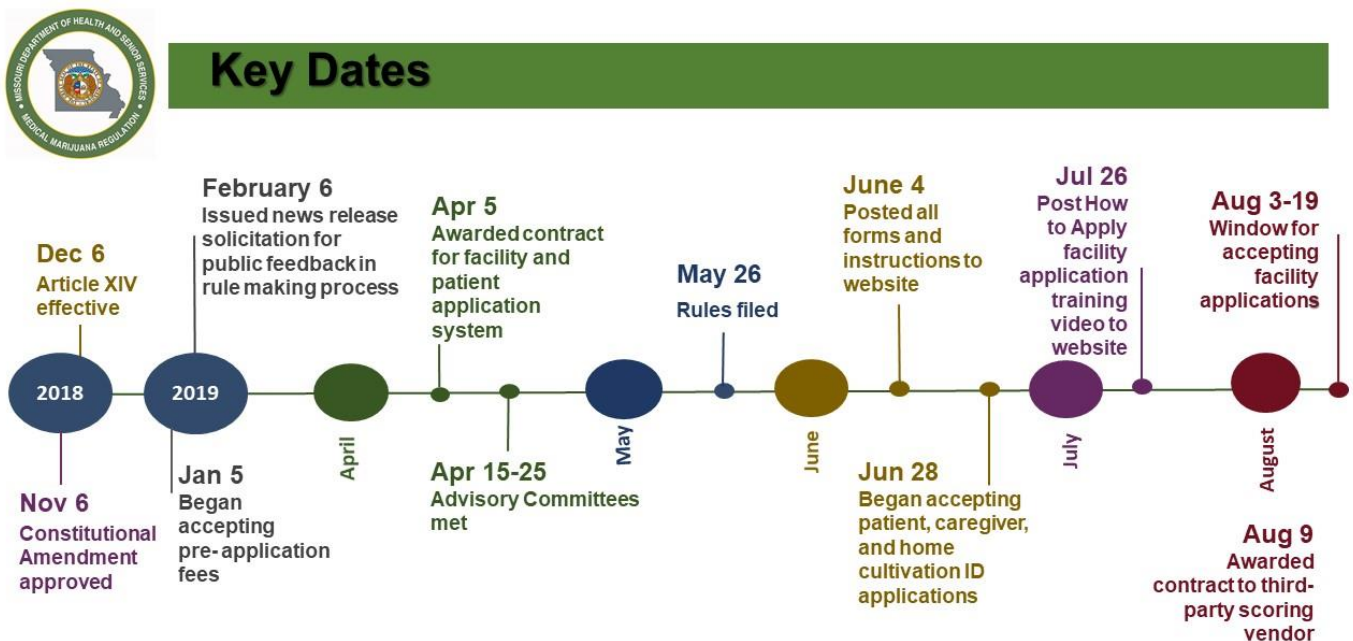
ORGANIZATIONAL DESIGN

The constitutionally specified program implementation deadlines necessitated swift and systematic action to design a framework and plan for the new MMRP. Within the first 30 days, the SMMR was staffed with a director and a deputy director who also serves as legal counsel. Within sixty days the principal assistant and the project director were staffed. These key members provided the initial leadership necessary to develop emergency rules, budget, communications, and contracts.

Implementation of the MMRP required timing priorities in a manner that allowed the SMMR to identify resources and accommodate peaks in workload before reaching stability. In the first 30 days, the SMMR, in conjunction with the Office of Administration, worked to solicit consultation services, and Deloitte Consulting LLP was contracted to design an organizational model and implementation plan under the direction of the SMMR project director. This model and plan are based on Article XIV and medical marijuana best practices obtained from research conducted by DHSS and Deloitte with other states. The organizational model is designed to be systematically scaled up throughout the implementation phase and is structured around program functions and strategic priorities. At full implementation, the SMMR will employ a staff of 52.

It was important to design an organizational model focused on critical functions aligned with the MMRP’s mission, vision, and strategic priorities. The organizational principals, design objectives, and criteria were developed to enable quick adaptation for flexibility and scalability, establish clear and consistent lines of responsibility to ensure transparency and accountability, and be customer oriented to streamline operations in delivery of services to patients, facilities, and the public. The organizational model and implementation plan established unit descriptions, measures, roles, and responsibilities. It also included workload projections and phased expansion of staff in order to successfully meet both consumer demand and Constitutional requirements. Additionally, it served as a tool for project tracking and identifying key implementation dates. Figure 2 highlights key dates for successfully navigating the MMRP’s implementation.

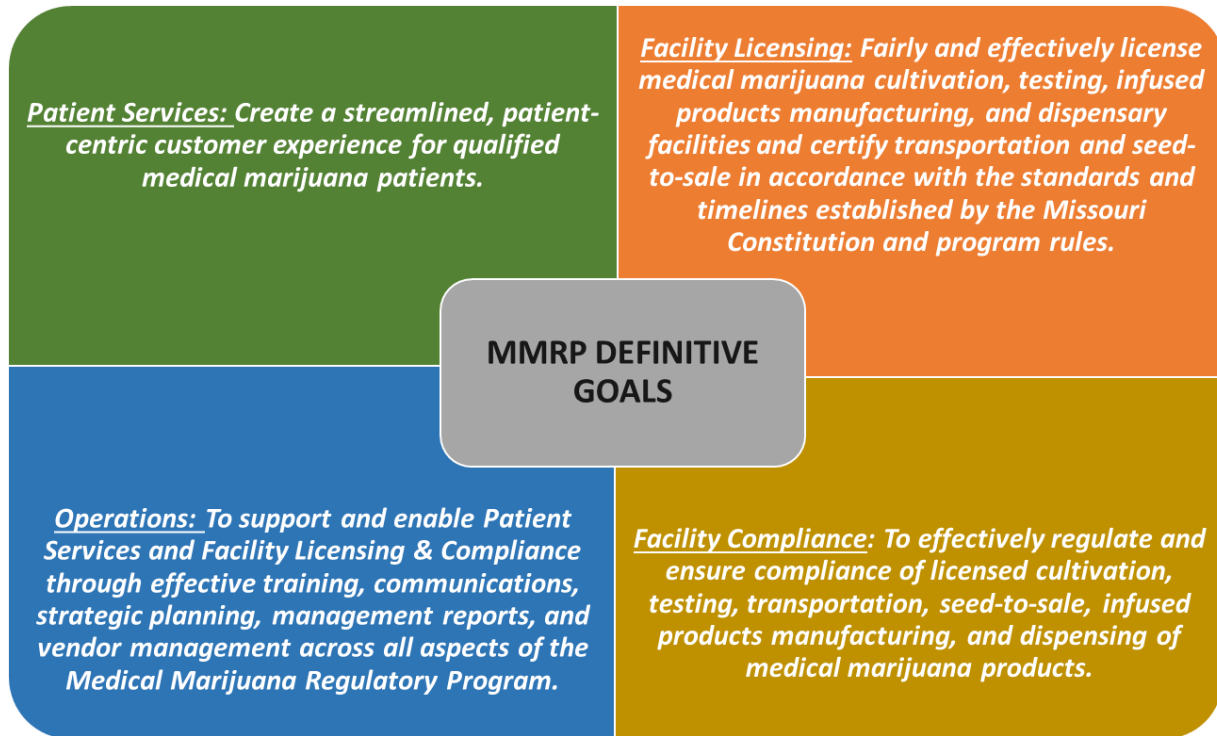
Figure 2: Key Implementation Dates



SMMR Functions

The SMMR's structure is organized to cover four primary functions: Patient Services, Operations, Facility Licensing, and Facility Compliance. Although the SMMR works in unison to meet overarching goals, each function has definitive goals identified to support the development and success of the MMRP. Figure 3 illustrates the definitive goal for each function within the SMMR. Additionally, the SMMR's operating model distinguishes the design, measures, roles, and responsibilities of each function.

Figure 3: MMRP Definitive Goals



Patient Services

The Patient Services Unit plays a pivotal role in meeting required constitutional dates, communicating complex rules to the public, and streamlining quality patient-centric services. The team serves as the frontline to the public, responsible for responding to stakeholder inquiries through all stages of the MMRP implementation.

By mid-May 2019, Patient Services included five employees. This was a pivotal point for Patient Services as it allowed the SMMR to establish what would become the primary avenue for addressing public inquiries. The original mechanism for accepting all public inquiries was through the Medical Marijuana Information email account. A call center was established on May 31, 2019, and members of the Patient Services Unit staff began accepting calls from the public through a toll free access line. The call center is operational Monday – Friday from 8:30 a.m. to 3:30 p.m. Inquiries outside this timeframe are routed through SMMR's email: medicalmarijuanainfo@health.mo.gov.

The Patient Services team was instrumental in testing the online patient registry system during its design phase to ensure the public had a user-friendly, efficient mechanism for submitting applications. They continue to evaluate and recommend improvements to the patient application process as well as identify needed communication materials such as user guides, tips sheets, and video tutorials.

At the end of PY19, Patient Services was comprised of 12 Patient Services Specialists charged with processing patient and caregiver applications. Article XIV specifies patient applications must be approved or denied within 30 days of receipt of a complete application. Patient services staff are responsible for ensuring all patient and caregiver applications meet the requirements of 19 CSR 30.95.030. Other duties include processing facility agent identification card applications (to commence in PY20) and answering agent inquiries; development of patient services' employee training, work processes and procedures; and working across the MMRP to assist in other areas, such as with special projects.

Operations

The Operations Unit is responsible for the cross-cutting administrative functions necessary to support implementation and maintenance of the MMRP. These functions include: budgetary oversight, performance metrics, public communication consisting of both webpage and public education material development, conducting internal and external training, contract management, special project coordination, compilation of reports including the Annual Report to the Governor, strategic planning, and program evaluation. The logistical support Operations provides is central to the overall success of the program and reinforces the guiding principle that collaboration and coordination with stakeholders leads to administrative efficiencies and has a positive impact on the SMMR's service delivery. The Operations team was fully staffed within the first 270 days, and is composed of three members.

Facility Licensing and Compliance Unit

The Facility Licensing and Facility Compliance functions are co-located organizationally in the Facility Licensing and Compliance Unit. These teams are under the direction of the Facility Licensing and Compliance Director and are supported by an administrative assistant. Planned staffing at full implementation is 27.

Facility Licensing

The Facility Licensing team is instrumental in fairly and effectively licensing facilities in a manner that conveys the SMMR's commitment to being transparent in its processes and accountable for its decisions. Facility Licensing is responsible for issuing medical marijuana facility licenses and certifications, facility education, response to applicant inquiries, license change application reviews, and facility licenses/certification renewals. Facility Licensing was fully staffed within the first 210 days. The team's efficient and adept execution of facility application reviews is a function aligning with the SMMR's strategic priority to make medical marijuana accessible for qualified patients.

Facility Compliance

The Facility Compliance team is responsible for creating compliance education, responding to compliance inquiries, commencement inspections, annual and renewal inspections, issuing violations and remediation directives, seed to sale monitoring, and compliance monitoring. Per the organizational model and implementation plan, this team will be the last portion of the MMRP developed by the SMMR. At the end of PY19, there were three compliance officers, and the SMMR was in the hiring process to expand this to fourteen compliance officers under the supervision of four regional managers. The compliance team is currently developing research-based policies and procedures consistent with carrying out the requirements of Article XIV and associated rules. The compliance team is vital to accomplishing the SMMR's strategic priority to enforce regulatory requirements and ensure compliance that keeps communities safe.

Promulgate Rules

Article XIV granted DHSS the authority and responsibility to promulgate rules necessary for the proper regulation and control of qualified patient access to medical marijuana. Within the first 30 days, DHSS filed emergency rules to effectuate the early pre-filing of facility application fees allowed by Article XIV. Within the first 60 days, the SMMR leadership spoke with medical marijuana regulators from other states, conducted extensive research on other states' regulations, and toured facilities and met with the regulating staff in another state. Within the first 90 days, DHSS began posting rule drafts of the regulatory framework necessary for implementing Article XIV. The entire set of rules applicable to the SMMR's first program year were filed on May 24, 2019, nine days before the constitutionally required deadline for filing these rules.

Market Study

The SMMR values research, analysis, and stakeholder engagement as essential to the creation of programmatic decisions that lead to effective, evidence-based practices. In order to inform several essential programmatic decisions, DHSS commissioned an independent market study to gain insight into the likely characteristics of Missouri's medical marijuana industry including the number of qualified patients within the first three years of the MMRP operations and the number of facilities necessary to support patient demand. This market study, "Missouri's Medical Marijuana Market: An Economic Analysis of Consumers, Producers, and Sellers" (Haslag, Crader & Balossi; 2019) was submitted to the SMMR in April 2019 and can be viewed at <https://health.mo.gov/safety/medical-marijuana/pdf/mu-market-study.pdf>. The market study provided a quantitative analysis using evidence across states in which medical marijuana is legal. It revealed the many competing forces that influence both producers and consumers. For consumers, the market study acknowledged the data collected by other states was incomplete and wisely contemplated projections at several different rates, including a rate that matches Missouri's experience so far. It also forecasted cultivation facility production to gauge how many facilities will be needed to meet patient demand. Ultimately, the market study educated DHSS and stakeholders on key factors that influence the medical marijuana market and serves as a great resource.

Public Forums and Advisory Committees

Stakeholder and public engagement to foster collaboration and ensure application of all available expertise was critically important in the promulgation of rules. Thus, the SMMR held public forums, attended and presented at numerous stakeholder events, and assembled advisory committees to gather input.

The SMMR held five public forums around the state to maximize public participation. These forums collectively engaged over 775 individuals representing constituents, law enforcement, local government, and other state agencies. Figure 4 illustrates the number of stakeholder attendees by location. Additionally, information regarding forum dates, video and audio coverage of forum meetings, and an online form for public submission of comments were posted on the MMRP website. The SMMR also accepted public comments by phone and email. All stakeholder and public comments were taken into consideration when promulgating rules.

Figure 4: Missouri Medical Marijuana Public Forum Events

City	Date	Attendance
Jefferson City	February 13, 2019	300+
Poplar Bluff	February 27, 2019	25
Saint Louis	February 28, 2019	60
Kansas City	March 6, 2019	250
Springfield	March 7, 2019	150

In addition to holding public forums, the SMMR Director traveled across the state delivering presentations and participating in panel discussions at 112 events in order to promote transparency by providing updates on the progression of the MMRP. This proactive communication strategy has profound benefits for both the public and the MMRP as it allowed the public to ask direct questions and increase knowledge in surrounding communities of MMRP priorities while grounding SMMR in local and regional impacts. Below is a bulleted summary of events:

SMMR Public Outreach Events

- **State Senator and Representatives town hall meetings**
- **Cannabis industry and associations meetings and seminars**
- **Prosecutors conferences**
- **Attorneys conferences**
- **MO Association of Treatment Court Professionals (MATCP)**
- **Law enforcement meetings (Missouri State Highway Patrol, sheriffs and police chiefs)**
- **Events for veterans**
- **Workforce meetings**
- **State and private business organizations meetings**
- **Missouri Banker's Association**
- **Long term care facilities, healthcare provider meetings**
- **Health departments conferences**
- **Local government conferences and meetings, such as the Association of Counties, Association of Counties County Commissioner Conference, Association of Cities and Planning and Zoning Commission meetings**
- **Municipal league meetings**
- **Chamber of Commerce meetings**
- **Kiwanis club meetings**
- **Guest speaking at a community college for student class credit**

The SMMR also established 10 advisory committees, one for each of the facility application scoring criteria established by constitution, to submit expert advice on the design of the numerical scoring system mandated by Article XIV in circumstances where there were more facility applications submitted than facility licenses available. These committees met in April 2019 and were tasked with reviewing and suggesting revisions to initial drafts of facility application scoring criteria questions. In addition to assistance with drafting the scoring criteria, the advisory committees also recommended weights for each scoring criteria question and topic. Each committee consisted of representatives from topic-relevant state agencies as well as members of the public with experience in the topic of their committee. All information regarding committee representatives, meeting dates, audio of meetings, and how to make public comments was posted to the MMRP website, where it shall remain available.

Rule Drafting and Filing

Article XIV mandated that all application forms and instructions for patients, caregivers, and facilities be made available by June 4, 2019. In order for the SMMR to create, receive, evaluate, and approve or deny each of these application types and for an applicant to determine whether applying was in his or her best interest, it was necessary that both the SMMR and the applicant know what would be required of them going forward. Patients and caregivers needed to know what would be required of them if they were approved as a patient or caregiver, and the SMMR needed to know how to evaluate whether an individual qualified and how to regulate that individual's authorizations as soon as the individual was approved. Relatedly, businesses needed to know what would be required of them if they were approved as a medical marijuana facility, and the SMMR needed to know how to evaluate whether the businesses were best qualified to operate as a particular type of facility in Missouri. All of this necessitated that a regulatory framework be in place on the day applications were made available. Therefore, the *de facto* deadline for rulemaking was June 4, 2019.

The time allowed for rulemaking was not enough time to draft and file rules through the normal rulemaking process and have them be final by June 4, 2019. Therefore, it was necessary that the first set of rules be emergency rules. However, the SMMR leadership was keenly aware that it would be inadvisable to create an entirely new Missouri industry without the public input that would normally be gathered through formal rulemaking. Therefore, the SMMR created a process for posting draft rules to the public for comment and then posting revised draft rules with comments incorporated, and continued this process of posting waves of drafts and revised drafts for each rule until the time came for filing the rules.

At the completion of this transparent and informed rulemaking process, the SMMR filed a full set of emergency rules to regulate the medical marijuana industry on time. It also filed proposed rules at the same time for the traditional rulemaking process so that they would be final in time to replace the emergency rules. The proposed rules proceeded through the formal rulemaking process according to schedule, and final orders of rulemaking were filed in October 2019, resulting in only minor changes to the rules. The fact that very few edits to the proposed rules were suggested during their public comment periods is a testament to the effectiveness of the SMMR's rulemaking process and the success of its public engagement strategy.

In October 2019, the SMMR filed Emergency Rule CSR 19 CSR30-95.028, Additional Licensing Procedures, which went into effect in December 2019. This rule informed the public of the process for confirmation and acceptance of facility license/certification and conditional denials. It provides those chosen for a facility license or certification with clear notification criteria and allows SMMR to quickly move on to denied applicants if a license becomes available during the year following initial licensure. The draft of the emergency rule was posted ahead of time for public comment just as the first set of emergency rules were. Comments were received and several changes were made to the draft rule in light of those comments.

Procure Facility Scoring and Information Technology Services

Article XIV established deadlines for accepting applications: 210 days to begin accepting patient, patient cultivator, and caregiver applications and 240 days to begin accepting facility cultivation, laboratory testing, dispensary, infused-product manufacturing, seed-to-sale, and transportation applications. SMMR acted swiftly to execute contractual relationships for processing applications, effectively scoring facility applications, and tracking seed-to-sale activities.

Facility Application Scoring Services

In order to learn from other states' experiences with awarding marijuana facility license, SMMR spoke with medical marijuana regulators, studied processes, and reviewed legal challenges in other states. Based on this research, DHSS elected to adopt an independent, third-party, blind scoring process for license applications as the approach most likely to ensure equity and eliminate bias in the facility license award process.

Through the State's competitive bidding procurement process, Wise Health Solutions was contracted to score facility license applications in accordance with Article XIV and associated rules. The blind scoring process includes a strict redaction methodology for applicants to maintain anonymity. The contract for Wise Health Solutions was issued the first week of August 2019.

Information Technology Solution Services

Within the first 90 days, the SMMR issued a bid solicitation for a vendor to host and manage the patient registry, facility licensing, and track and trace database, collectively referred to as the Missouri Medical Marijuana Information Solution. Due to constitutional deadlines, the SMMR included expedited implementation in the contract for patient and facility applications. The central objective was to promptly implement a secure, practical system for efficiently processing patient and facility applications and to establish the constitutionally mandated, statewide medical marijuana track and trace system.

The State of Missouri awarded a contract to vendor METRC LLC and its sub-contractor, Complia, on April 5, 2019 to provide DHSS with a secure, online registry system for submission of patient and facility applications. However, work on the design and implementation of the registry system was immediately halted by more than a month while the contract award was unsuccessfully protested by another bidder. Although this delay created additional challenges, the online registry system launched on June 28, 2019 allowing patients and caregivers to submit applications six days earlier than constitutionally required. Due to the hard work of the SMMR team and its IT system partner, Complia, this implementation timeframe broke nationwide records for similar system implementations.

The patient services portion of the IT solution is designed to allow the SMMR staff to review, approve, and deny patient, caregiver, and patient cultivation applications within the registry. This system was crucial in enabling the SMMR staff to approve patient applications within the constitutionally required 30 days. Additionally, the database allows facilities to establish secure user accounts for submitting and updating/editing an application for licensure and includes a sophisticated integration with the DHSS third-party payment system to accept electronic payment of application fees.

Another key element of the IT solution is the ability to trace medical marijuana product from seed or immature plant to point of sale including capacity for: product recalls, recording tetrahydrocannabinol (THC) and potency levels, registering product packaging, ensuring products have met testing requirements, and accountability and traceability functions to assist the State in discovering and eliminating illegal activity. This function is critical to regulate the medical marijuana industry to comply with Missouri law and keep communities safe.

Develop Forms, Certificates, Licenses, Identification Cards & Applications

The facility pre-file payment procedure was posted to the MMRP website within the first 30 days. By June 4, 2019, sample facility application forms with instructions as well as sample and actual patient, caregiver, parental/legal guardian, and physician certification forms and instructions were posted to the SMMR program website. Additionally, SMMR created dedicated webpages – How to Apply for patients and How to Apply for facilities – that contained forms, tutorials, fact sheets, frequently asked questions, and instructions to assist applicants in submission of complete applications.

Patient Services Forms

Patients may apply for a DHSS-issued medical marijuana identification (ID) card if they are Missouri residents and are certified by a Missouri licensed physician who attests the patient has a qualifying condition. Patients may designate up to two caregivers, who are over the age of 21 years, to purchase and/or cultivate medical marijuana on their behalf. Minors are allowed to use medical marijuana under the supervision of a parent or legal guardian. Minors are individuals under the age of 18 who have not been legally emancipated.

Physician Certification and Attestation

Article XIV grants state-licensed Medical Doctors (MD) or Doctors of Osteopathy (DO) the right to recommend medical marijuana to patients with a qualifying condition. As part of the physician certification, physicians are required to attest that certain statements are true. These attestations provide a framework for the certification process and convey expectations for the quality of care medical marijuana patients should receive. Any physician who falsely attests to meeting these requirements may be subject to sanctions or penalties from the Board of Healing Arts per applicable laws and regulations. These expectations are summarized in Figure 5 as follows:

Figure 5: Physician Attestation

- | |
|---|
| <input checked="" type="checkbox"/> In the case of non-emancipated individuals under the age of eighteen, physicians must receive written consent of a custodial parent or legal guardian who will serve as a primary caregiver for the qualifying patient before certifying that patient. |
| <input checked="" type="checkbox"/> The physician must meet with and examine the qualifying patient. |
| <input checked="" type="checkbox"/> The physician must review the qualifying patient's medical records or medical history and the qualifying patient's current medications and allergies to medications. |
| <input checked="" type="checkbox"/> The physician must have a conversation with the qualifying patient (or the qualifying patient's custodial parent or legal guardian) about the patient's current symptoms. |
| <input checked="" type="checkbox"/> The physician must create a medical record for the qualifying patient regarding the meeting and maintain the qualifying patient's medical record as required in 334.097, RSMo. |
| <input checked="" type="checkbox"/> The physician must have a conversation with the qualifying patient (or the qualifying patient's custodial parent or legal guardian) about the risks associated with medical marijuana, including any known contraindications applicable to the patient. |
| <input checked="" type="checkbox"/> The physician must have a conversation with the qualifying patient (or the qualifying patient's custodial parent or legal guardian) about the risks of medical marijuana use to fetuses and to breastfeeding infants, if applicable. |

All expectations are conveyed to each physician who signs a certification in that they must specifically attest they have complied with each expectation. Additionally, these expectations regarding the standard of care that medical marijuana patients should receive are communicated on the SMMR website in the section of the site dedicated to physician information.

Patient/Caregiver Cultivation

Any patient or caregiver interested in cultivation may apply for that authorization within certain parameters. For instance, all patient/caregiver cultivators agree during the application process to make their cultivation space available for inspection. Furthermore, individuals may only cultivate a certain number of plants. Most importantly, all licensed patient/caregiver cultivation shall take place in an enclosed, locked facility, as required by Article XIV and defined in 19 CSR 30-95.010, which shall include:

- Secure, locked space with access limited to only the authorized patient and/or caregiver;
- Clearly labeled plants; and
- Display of the cultivation authorization form;

Facility Licensing

Article XIV allowed cultivation, manufacturing, and dispensary applicants to pre-file non-refundable facility application fees. The deadline for the SMMR to begin accepting these fees was January 5, 2019. See Figure 6 below, which illustrates the number of pre-filed application fees collected prior to August 3, 2019, the day SMMR began accepting applications.

While not a requirement and providing no benefit to the applicant, 543 applicants chose to pre-file their application fees.

Figure 6: Pre-Filed Facility Stats

License Type	Number of Pre-filed Facilities	Pre-filed facility fees
Cultivation Facility	164	\$1,640,000
Dispensary Facility	334	\$2,004,000
Manufacturing Facility	94	\$564,000

Prior to accepting facility applications, significant resources were devoted to guiding facility applicants through the application process. Dozens of FAQs were published to respond to specific questions regarding the process and the content of the application. The SMMR took great pains to ensure that all applicants would have access to the same guidance by updating the FAQs with responses to questions as soon as practicable after a question arose.

Video tutorials were posted on the How to Apply webpage for facilities and contained information regarding how to: complete required worksheets, properly redact documents for the blind scoring process, navigate the online application registry, upload required documents, and submit applications. In addition, a visual representation titled “Roadmap to Licensure” was displayed on the How to Apply webpage. This visual provided a complete overview of the step-by-step process for submitting a facility application. The information provided can be seen in Figure 7.

Figure 7: Roadmap to Licensure

ROADMAP TO LICENSURE
Step 1: Complete and save required worksheets
Step 2: Prepare and obtain required documentation:
<ul style="list-style-type: none"> ➤ Completed Ownership Structure form. ➤ Prepare written description or visual depiction of ownership structure. ➤ If applicable, gather proof of Missouri residency. ➤ If applicable, obtain local government requirement replacing DHSS 1,000 ft. rule OR obtain map of surrounding proposed address showing compliance with DHSS 1,000 ft. rule. ➤ Prepare descriptions, schematics or blueprints for proposed facility. ➤ If applicable, demonstrate compliance with local zoning restrictions. ➤ If applicable, submit written explanation of how facility is under substantial common control, with supporting documentation.
Step 3: Gather information on facility organization:
<ul style="list-style-type: none"> ➤ Gather data for all individuals listed in the facility’s ownership. ➤ Gather data for facilities under substantially common control as applicant entity.
Step 4: Submit application, required documentation, and fees to Missouri MMRP Portal:
<ul style="list-style-type: none"> ➤ Create account in the Missouri MMRP Portal and enter/attach required documentation and pay fees.
CULTIVATION, DISPENSARY, MANUFACTURING AND TESTING FACILITIES

Fees

DHSS is granted authority to assess and collect application fees and administrative and processing fees. Fees are collected from patient, facility, and facility agent (employee) applications. DHSS currently utilizes this revenue stream to account for all its expenditures to administer the MMRP. If necessary in the future to cover its expenses, the SMMR may also access the revenues generated by a four percent tax on the retail sale of medical marijuana.

There are currently 10 categories of fees. Figure 8 provides the license/certification type and the associated application and annual fees through January 2022. Application and license fees will be increased or decreased each year by the percentage of the increase or decrease from the end of the previous calendar year of the Consumer Price Index, or successor index as published by the U.S. Department of Labor, or its successor agency. Facility licenses and certifications are valid for three years, and Seed to Sale certification is indefinite. Patient and caregiver authorizations are valid for one year.

Figure 8: License and Certification Application Fees

Fee Type	Application Fee (12/2018 – 12/2021)	Annual Fee	Renewal Fee	New Application Fees (1/2022)
Cultivation Facility *	\$ 10,000.00	\$ 25,000.00	\$ 5,000.00	\$ 5,000.00
Dispensary Facility *	\$ 6,000.00	\$ 10,000.00	\$ 3,000.00	\$ 3,000.00
Manufacturing Facility *	\$ 6,000.00	\$ 10,000.00	\$ 3,000.00	\$ 3,000.00
Laboratory Testing Facility *	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00
Facility Agent *	\$ 75.00	\$ -	\$ 75.00	\$ 75.00
Seed-to-Sale †	\$ 5,000.00	\$ 5,000.00		\$ 5,000.00
Transporter †	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00
Patient *	\$ 25.00	\$ -	\$ 25.00	\$ -
Caregiver *	\$ 25.00	\$ -	\$ 25.00	\$ -
Home Cultivation *	\$ 100.00	\$ -	\$ 100.00	\$ -
* License				
† Certification				
▪ A facility is licensed for 3 years				
▪ A patient, caregiver, and cultivator is licensed yearly				
▪ Annual fees are due 30 days after a facility is licensed and then yearly thereafter				

SMMR began accepting patient, caregiver, and patient/caregiver cultivation applications on June 28, 2019. It is important to note that revenues received will not always be equal to the number of applications received multiplied by the corresponding fee due to partial payments, abandoned or withdrawn applications, and refunds, where allowable by law. Figure 9 provides a breakdown of facility and patient fee revenues received for PY19.

Figure 9: Patient and Facility Fees Collected

Fee Type	Revenue Amount for Program Year 2019 December 6, 2018 – December 5, 2019
Cultivation Facility	\$6,404,694.02
Dispensary Facility	\$7,872,000.00
Infused-Product Facility	\$2,702,000.00
Laboratory Testing Facility	\$85,000.00
Seed to Sale	\$50,000.00
Transporter	\$90,000.00
Patient Identification Card	\$586,375.00
Cultivation Identification Card	\$783,450.00
Caregiver Identification Card	\$15,925.00
Total	\$18,723,704.63

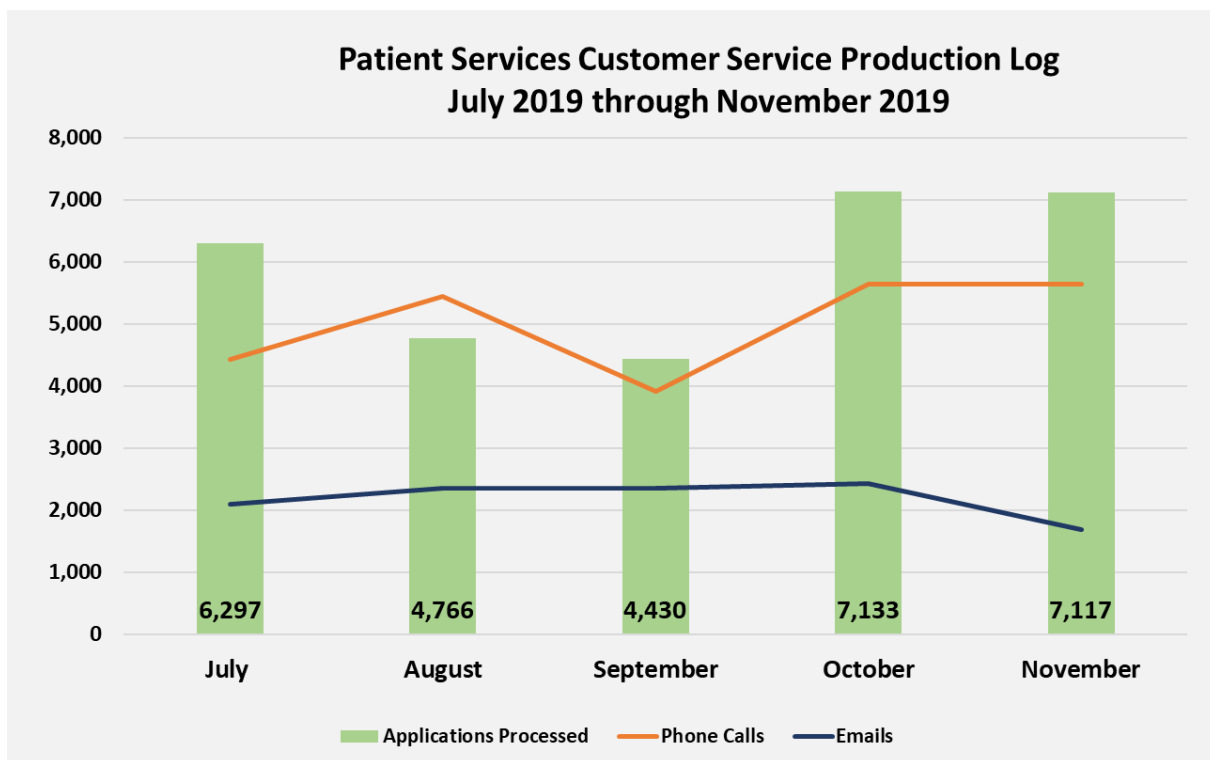
Grant or Refuse Licenses & Certifications

Article XIV requires that all complete patient and patient caregiver applications be approved or denied within 30 days of submission and all complete facility licenses and certifications be granted or refused within 150 days from submission during the facility application period. This section represents data and statistics related to the efficient discharge of this particular responsibility.

Patient and Caregiver Applications

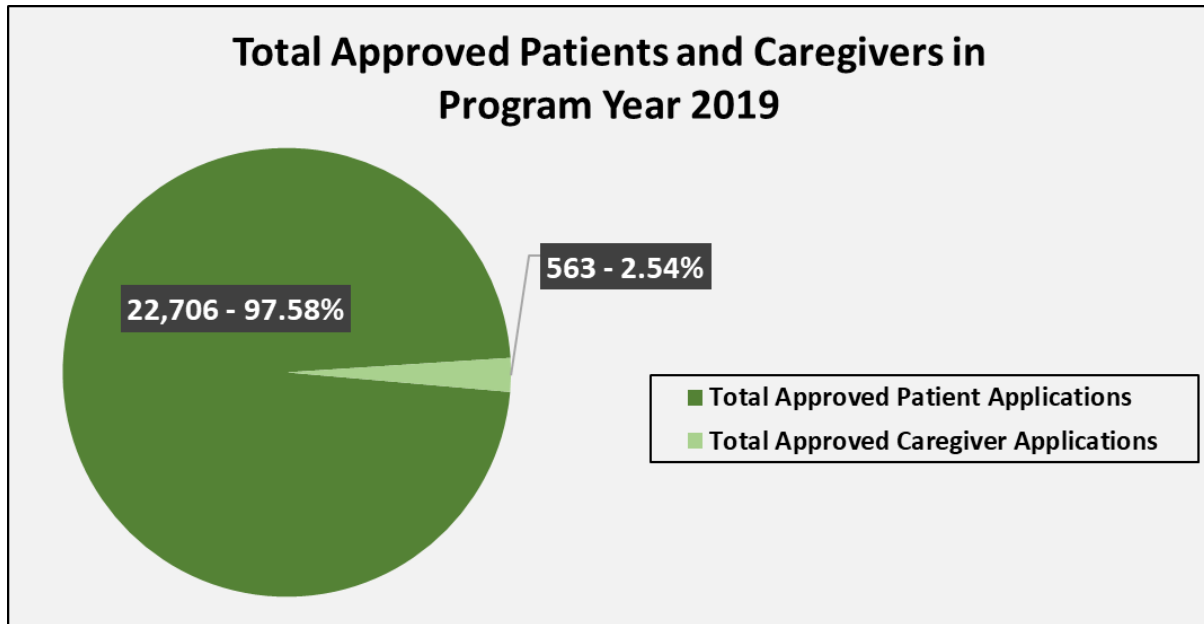
From June 28, 2019 through December 5, 2019, the SMMR received 25,021 patient and patient caregiver applications. As of December 5, 2019, 100 percent of applications received have been processed within the 30 day required timeframe. Patient Services has successfully maintained approving or denying 100 percent of all complete applications received as constitutionally prescribed while simultaneously responding to a high volume of calls and email inquiries. From June 2019 through November 2019, patient services received and responded to an average of more than 2,000 emails monthly. Figure 10 highlights the volume of applications, calls, and emails received by month from July 2019 through November 2019.

Figure 10: Number of Patient and Caregiver Applications, Calls, and Emails



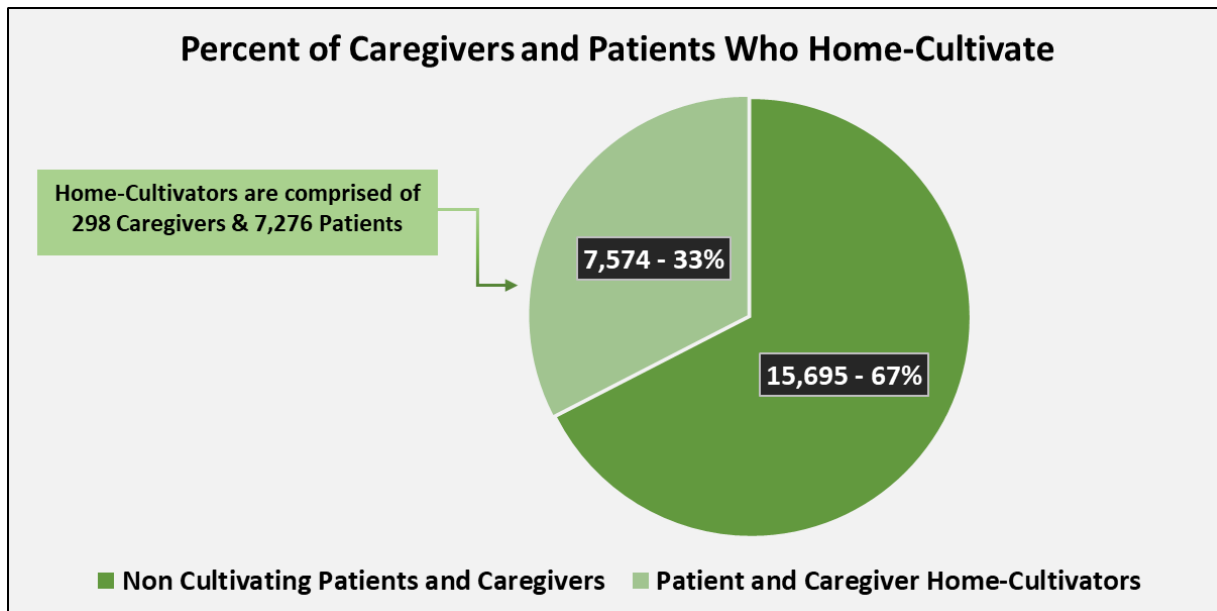
From June 2019 – December 5, 2019, the Patient Services Unit approved 22,706 patient applications and 563 caregiver applications. Figure 11 compares the number and percentage of patient and caregiver applications approved.

Figure 11: Approved Patient and Caregiver Applications



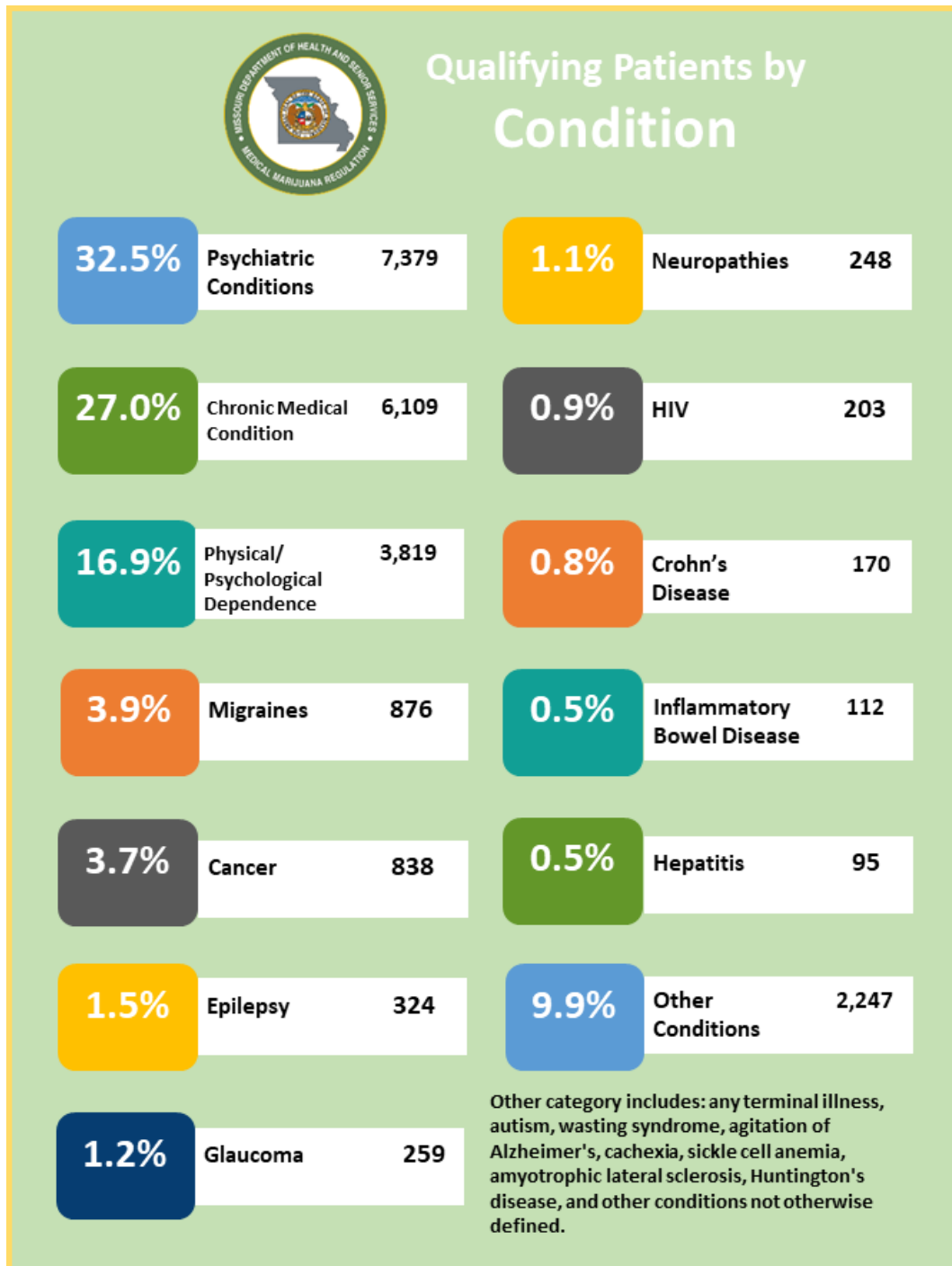
Of the total 23,269 approved applications, 33 percent were also approved to cultivate. Figure 12 is a percentage of Caregivers and Patients Who Cultivate.

Figure 12: Percent of Caregivers and Patients Who Cultivate



From June 28, 2019, through December 5, 2019, approved qualifying patients were certified for qualifying conditions as illustrated below in Figure 13. There are nine constitutionally prescribed categories of qualifying conditions, with subcategories, all of which are noted on the Physician Certification Form as applicable. Physicians are to note both the constitutional category and specify the specific condition therein. Of those specific conditions reported for approved patients, the two most prominent categories were psychiatric conditions (32.5 percent) and chronic medical conditions (27 percent).

Figure 13: Qualified Patients by Condition



From June 28, 2019 through December 5, 2019, most approved qualifying patients applications were submitted by individuals between the ages of 30 and 39 years of age (21.77 percent), followed by individuals between the ages of 50 and 59 years of age (19.22 percent). Less than one percent of approved qualified applications were received for individuals under the age of 18. Figure 14 provides the complete data for percentages of approved qualified patients by age.

Figure 14: Qualified Patients by Age

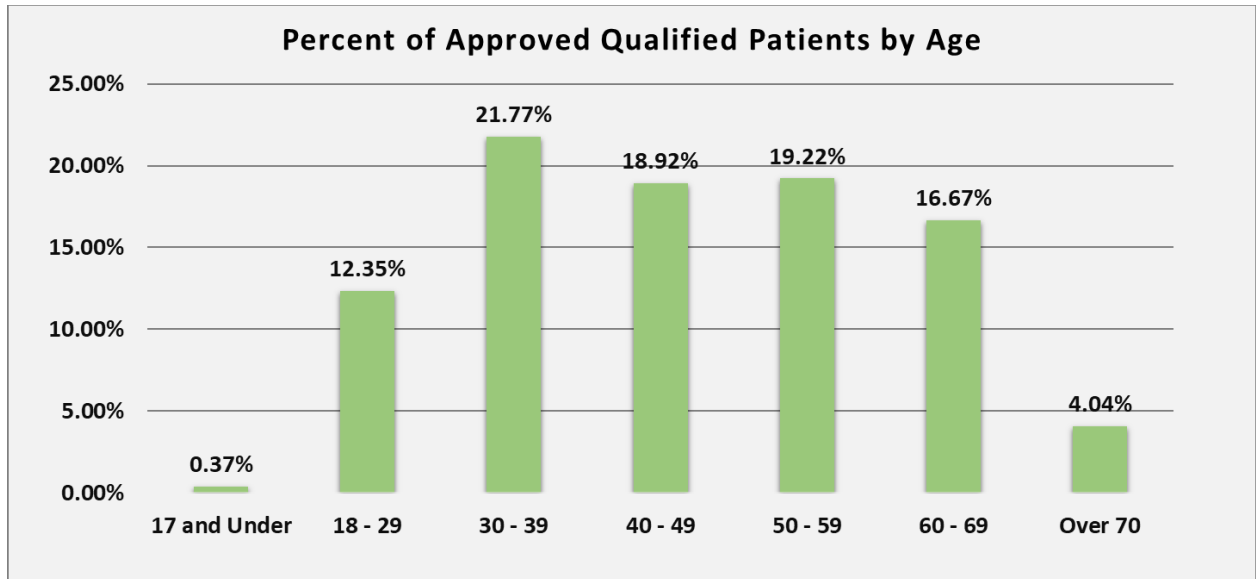
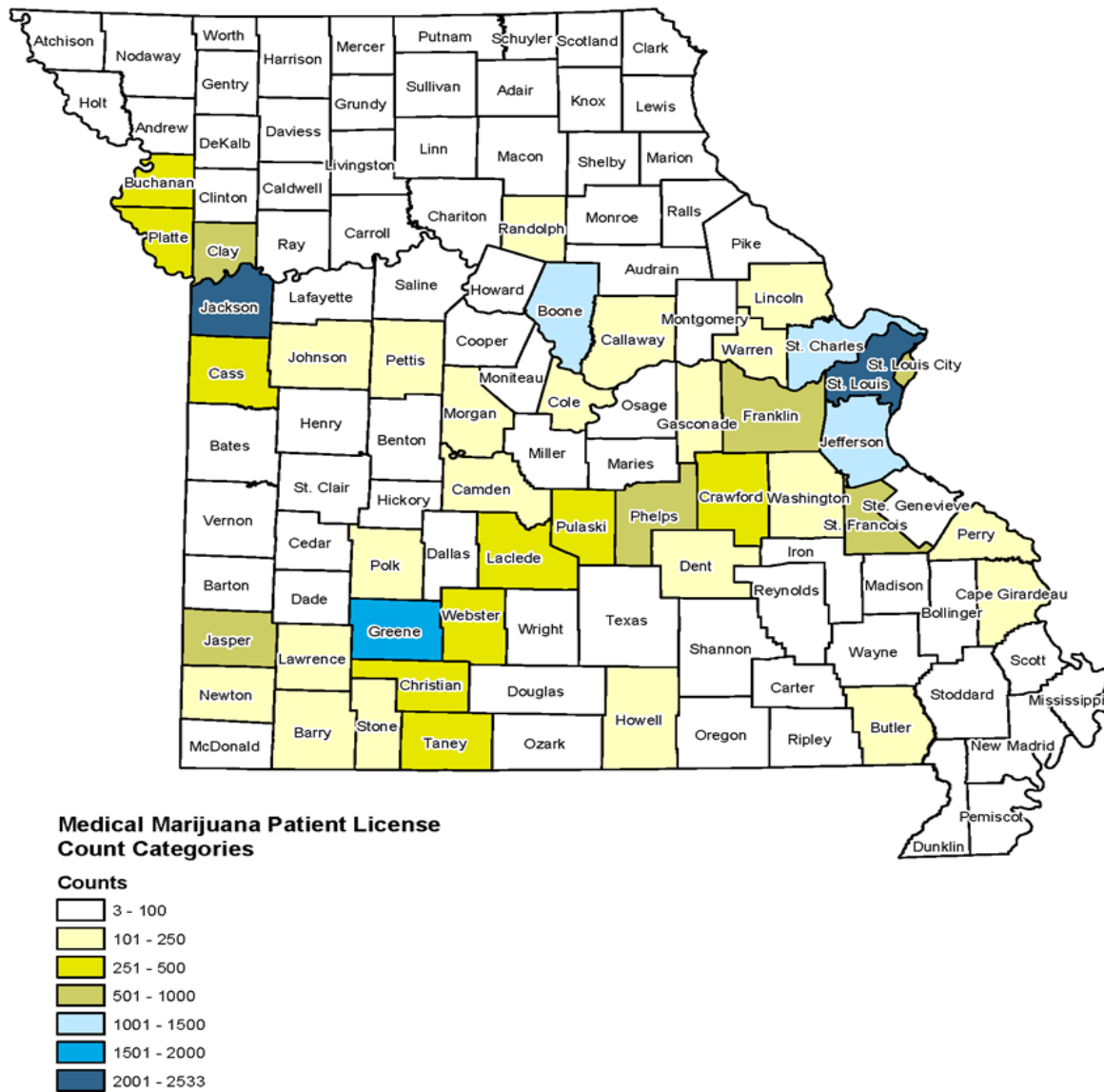


Figure 15 represents the distribution of qualified patients in Missouri by county. From June 28, 2019, through December 5, 2019, most Missouri counties had between three and 250 qualified patients. The counties with the highest number of qualified patients, ranging from 2,001-2,533, were those with a densely populated core and included Jackson County, St. Louis City, and St. Louis County.

Figure 15: Qualified Patients by County of Residence

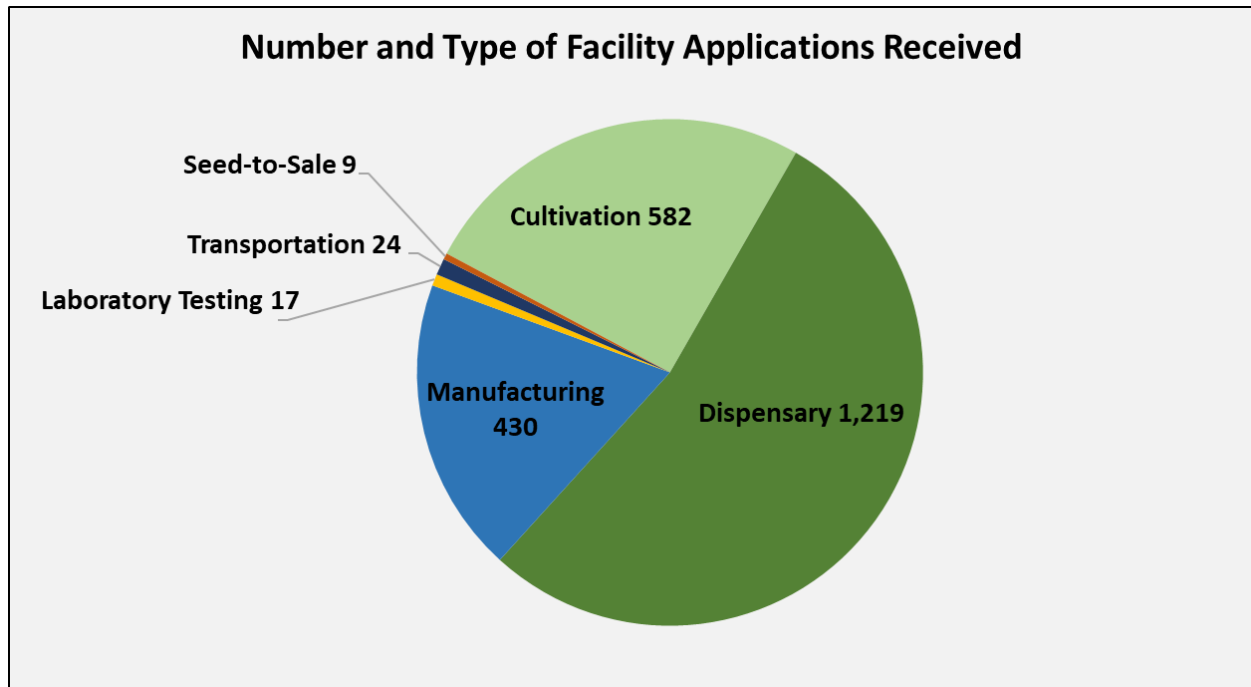
Medical Marijuana Patient License Distribution in Missouri



Facility Licensing Applications

Pursuant to authority in Article XIV, the SMMR's rules alerted applicants and the public that the minimum number of licenses in Article XIV would be issued - 60 cultivation, 86 infused-product manufacturing, and 192 dispensaries – as well as 10 laboratory testing certifications. Beginning the MMRP with the minimum number of licenses proposed in Article XIV allows the SMMR to provide more medical marijuana than necessary to meet demand for several years. This approach also allows the SMMR to establish compliance and enforcement measures mandated by Article XIV that protect against unsafe product and diversion of product to the black market. The limits allow for safe regulation while ensuring patient access in alignment with Article XIV and the DHSS mission of “protecting health and keeping the people of Missouri safe.” The SMMR received over 2,270 facility applications, over 1,000 more than expected. Article XIV did not establish minimums for transportation or seed-to-sale certifications or subject those applicants to a scoring system, and the SMMR continues to accept these applications. Figure 16 provides the number of applications received during PY19 by facility type.

Figure 16: Facility Applications Received



The Facility Licensing team began its review for application completeness on August 3, 2019. Per Article XIV and the associated rules, the SMMR has 150 days from the day an application was complete to approve or deny the application.

Hundreds of detailed processes and procedures were developed during the first year of program operation for facility application submission and review. These processes and procedures were the framework for ensuring each applicant had an equal opportunity to submit a fully compliant application, for accurately determining whether an application met minimum qualifications, and for effectively evaluating all scoring criteria questions for each of the more than 2,270 applications received. The Facility License and Compliance Unit and legal staff went to great lengths to design an application review process that could not be influenced by bias or conflict of interest.

For instance, the blind scoring review process was designed to ensure that all information provided from applicants was reviewed and scored solely on merit. Each portion of the application subject to scoring was grouped into worksheets and scored by individual reviewers who were assigned questions based on their areas of expertise. Reviewers were provided scoring criteria from the SMMR to use in assigning a score to ensure consistency. Application reviewers did not have access to identifying information about the applicant entity or persons applying. The scoring method, questions, and question/topic point values were posted on the SMMR's website months in advance of the open application period allowing all prospective applicants the same opportunity to review the evaluation criteria questions and begin constructing their response.

Facility License and Compliance staff conducted initial application reviews for every application in the first few weeks of the application review process. Facilities that were rejected, by rule, were given seven calendar days to modify and resubmit their applications. Upon resubmission, staff downloaded, saved, and uploaded over 76,000 redacted worksheets and worksheet attachments to a secure server from the application registry in order to transfer that information to the independent application scoring vendor. Coinciding with the scoring process, the Facility License and Compliance staff conducted a second review of all resubmitted applications against minimum requirements as stated in rule. Processes were developed and implemented for the consistent review of minimum qualifications. Any facility application failing to meet the minimum requirements following staff review were forwarded to the SMMR's legal team for verification of the applicant's failure to meet minimum qualifications. Less than 11 percent of applicants were denied for failure to meet minimum requirements.

Pursuant to the MMRP's regulations, the Facility Licensing team developed a process to review all applicants' final score and rank to determine which applicants would receive the prescribed minimum licenses for each facility type. Prior to licensure, after all scoring was complete, the SMMR applied score adjustments as outlined in 19 CSR 30-95.025.

In the case of all facility applicants, additional points are awarded to the applicants' final blind score based on the following:

- A facility seeking a license to locate within a zip code area that has an employment rate of 85 percent to 89.9 percent will receive a scoring increase of 30 percent for the average initial score of all applicants of the same facility type within the evaluation criteria topic regarding potential for positive economic impact in the site community; and
- A facility seeking a license to locate within a zip code area that has an employment rate of zero to 84.9 percent will receive a scoring increase of 40 percent for the average initial score of all applicants of the same facility type within the evaluation criteria topic regarding potential for positive economic impact in the site community.

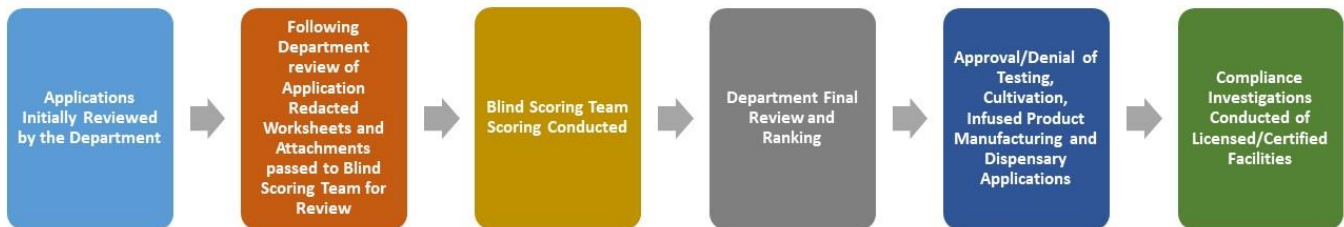
In the case of dispensary applicants, additional points were awarded to the applicants' final blind score based on the following:

- A score adjustment was applied to the highest ranked applicant within each House District whose location was either in a non-segmented Congressional District or, when in a segmented Congressional District, whose location was in the segment of that House District with the highest population.
- The score adjustment value was determined by obtaining the average of the final blind scores of the top 24 ranked dispensaries in each congressional district multiplied by five percent.

House and Congressional Districts were identified and confirmed by the State of Missouri Geospatial Information Systems (GIS) team using the facility physical location provided by the applicant. In cases where the facility address could not be verified, such as with parcels that did not have an address assigned, the latitude and longitude coordinates provided by the applicant were used to identify the House and Senate District.

The resulting final scores for all facility license types were sorted from highest to lowest. A facility who failed to meet the minimum requirements by rule or applicants who exceeded the maximum number of licenses allowed per facility type under substantial common control were denied. In cases where an entity under substantially common control applied for more than the number of licenses per category, only the highest ranked applicants among those with substantial common control were issued licenses, up to the maximum allowed. Per Article XIV, an entity under substantially common control is allowed up to three cultivation, three infused product manufacturing, and five dispensary licenses. Figure 17 also appeared on the How to Apply webpage for facilities and represents the lifecycle process for facility application review.

**Figure 17: Facility Application Review Lifecycle
Testing, Cultivation, Infused Product Manufacturing, Dispensary**



Suspend, Fine, Restrict, or Revoke Licenses & Certifications

Violations and Penalties

The SMMR is granted the authority to suspend, restrict, and revoke a license or identification card, as necessary, and impose administrative penalties in certain circumstances. Rules regarding violations and penalties are posted with all other SMMR regulations on the SMMR website. No licenses were suspended, restricted, or revoked during PY19.

Patient and Caregiver Enforcement

The Patient Services team is responsible for enforcing the rules associated with patient and caregiver identification cards. Rule 19 CSR 30-95.30, Qualifying Patient/Primary Caregiver, explains the identification card application requirements and potential reasons for denial as well as potential reasons for revocation. Figure 18 provides an overview of violation types and the associated administrative actions or penalties that may be enforced.

Figure 18: Patient, Caregiver, and Patient/Caregiver Cultivation Violations and Penalties

Violation	Penalty
If a card holder violates any provision in 19 CSR 30-95.010	⇒ Revoke identification card
If a card holder is found to be in possession of an amount of marijuana greater than the medical marijuana legal limit applicable to that individual	⇒ Revoke identification card for up to one (1) year ⇒ Fine of two hundred dollars (\$200)
If a card holder is convicted of, pleads guilty to, or receives a suspended imposition of sentence for a violation of section 579.020, 579.065, or 579.068, RSMo or for a violation of a similar law of another state	⇒ Permanent revocation of identification card absent a gubernatorial pardon or expungement
If a patient cultivation identification card holder fails to immediately make available access to his or her patient cultivation facility upon request from the department	⇒ Revoke identification card
If medical marijuana is stolen or lost, is identifiable as medical marijuana purchased by a particular qualifying patient or primary caregiver, is discovered in the possession of an individual who is not the qualifying patient or primary caregiver authorized to possess that medical marijuana, and was not timely reported as stolen or lost by the qualifying patient or primary caregiver authorized to possess that medical marijuana, the qualifying patient's or primary caregiver's identification card may be revoked.	⇒ Revoke identification card
If a qualifying patient or primary caregiver uses combustible gases or other dangerous materials to extract resins from marijuana	⇒ Revoke identification card for up to one (1) year ⇒ Fine of two hundred dollars (\$200)

While the Patient Services team makes every effort to educate patients and caregivers about all aspects of Article XIV and the associated rules, issues related to medical marijuana possession are largely outside the purview of DHSS. Though DHSS may offer guidance to stakeholders regarding how to interpret the possession provisions of Article XIV, law enforcement and the courts will be the entities ultimately responsible for interpreting and enforcing possession laws. Figure 19 provides an overview of legal purchase and possession for medical marijuana qualified card holders in Missouri.

Figure 19: Patient, Caregiver, and Cultivator Cardholder Purchase and Possession Regulation

Purchase Amounts:

- Qualified patients or their caregivers may purchase up to four ounces of dried, unprocessed marijuana, or its equivalent, in a 30 day period
- If a patient requires more than this amount, two independent physician certifications stating the amount needed must be submitted with the patient application.

Legal possession in Missouri applies to:

- Only patients and caregivers with a valid DHSS issued ID card, or
- A person with a pending qualified patient or caregiver application that has been filed with the MMMP's patient registry as long as they are able to produce their valid physician certification and show proof of pending registry.
- An equivalent ID card or authorization issued by another state or political subdivision of another state will also meet the requirements for possession.

Possession amounts:

- In the case of qualifying patients who do not cultivate or have medical marijuana cultivated on their behalf, up to a 60-day supply (eight ounces) of dried, unprocessed marijuana per qualifying patient, or its equivalent; or
- Authorized cultivator may have up to a 90-day supply (12 ounces) of dried, unprocessed marijuana or its equivalent, so long as the supply of medical marijuana cultivated by the qualifying patients or primary caregivers remains on property under their control. All plants must be kept in a secure, locked facility and be clearly labeled.

Medical marijuana purchased from a licensed dispensary or produced from authorized home cultivation cannot be:

- Transported across state lines; or
 - Sold, given away, or otherwise shared with any individual other than the licensed patient for whom the medical marijuana was intended.
- ❖ *All purchased medical marijuana must remain in or with its original packaging.*

Facility Enforcement

The Facility Compliance team is responsible for enforcing the rules associated with all facility licenses and certifications. Figure 20 provides an overview of violation types and the associated administrative actions or penalties that may be enforced.

Figure 20: Facility Violations and Penalties

Violation	Penalty
A facility uses combustible gases or other dangerous materials to extract resins from marijuana without a manufacturing facility license	<ul style="list-style-type: none"> ⇒ License may be suspended or revoked ⇒ Fine of ten thousand dollars (\$10,000)
A facility violates any provision in 19 CSR 30-95.010 or fails to comply with a corrective action plan	<ul style="list-style-type: none"> ⇒ License may be suspended or revoked
A facility packages medical marijuana in a false or misleading manner, or in any manner designed to cause confusion between a marijuana product and any product not containing marijuana	<ul style="list-style-type: none"> ⇒ License may be suspended or revoked ⇒ Fine of five thousand (\$5,000) for each category of improperly packaged product ⇒ Improperly packaged medical marijuana will be recalled for repackaging or disposal, at the department’s discretion
A facility is granted a license or certification but has not passed a commencement inspection within one (1) year of the department issuing the license	<ul style="list-style-type: none"> ⇒ License may be revoked
A facility fails to comply with a department order to immediately suspend all or a part of its operations	<ul style="list-style-type: none"> ⇒ License shall be revoked
A facility or a facility employee fails to comply with seed-to-sale tracking requirements or intentionally misuses or falsifies seed-to-sale tracking data	<ul style="list-style-type: none"> ⇒ License may be revoked

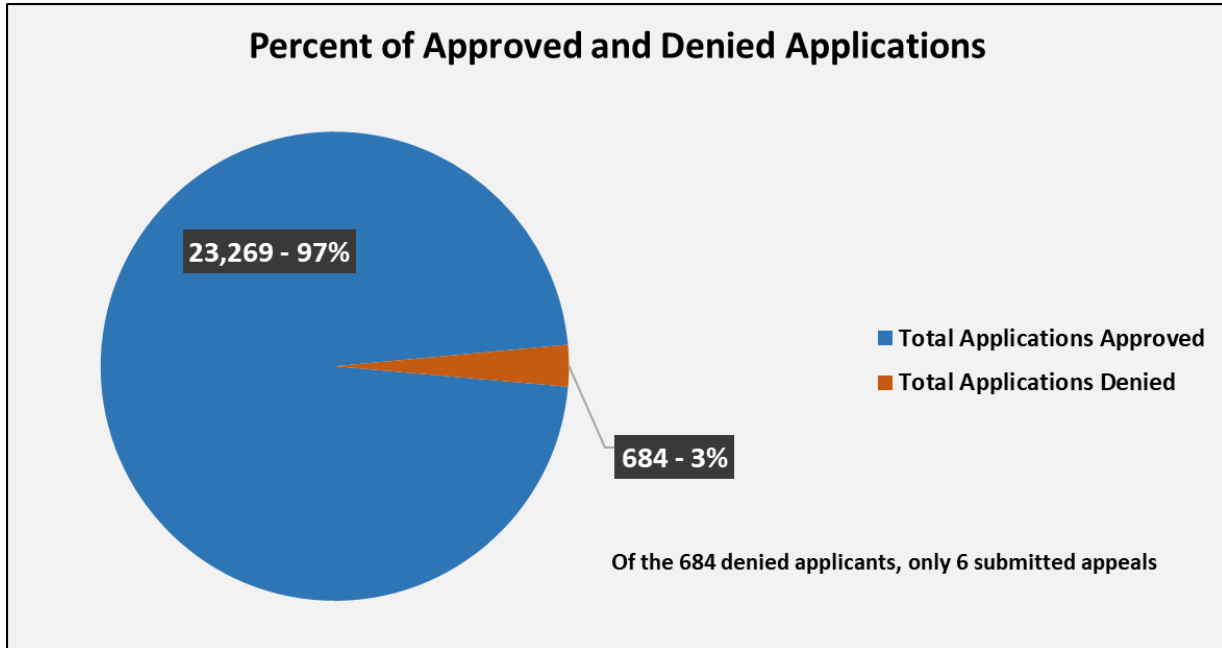
Administrative Hearings

One of the SMMR’s goals is to enforce regulatory requirements in a firm, transparent, and consistent manner. SMMR effectuates this goal by having defined policies and consistent processes that allow every applicant to know and understand what is required for an application to be approved. This same approach allows every approved card holder and facility a reasonable opportunity to understand the expectations, foresee consequences of falling short of those expectations, and correct any deviations from the expectations before those deviations result in consequences. However, when it becomes necessary to deny an application or suspend or revoke a card, license, or certification, these actions may be appealed, per Article XIV.

Appeals of denials, suspensions, and revocations are made through the State of Missouri Administrative Hearings Commission (AHC). The AHC acts as a neutral and independent hearing officer to impartially review the SMMR’s decisions. The right to an administrative hearing process is contingent on the individual or business filing a petition with the AHC within 30 days after the SMMR’s decision is sent to the individual or business.

A very small number of patient/caregiver application appeals occurred in PY19. Of the six total patient/caregiver application appeals received, two were resolved without hearing, and four were dismissed as the patients did not pursue them. Figure 21 displays the percent of denied patient applications and the number of appeals that occurred from June 28, 2019 through December 05, 2019.

Figure 21: Percent of Approved and Denied Patient Services Applications



* Patient service applications include: patients, caregivers, and patient/caregiver cultivation.

As the facility licensure period had not concluded by December 5, 2019, there are no AHC appeals for the following: license suspension and revocation and/or related fines for regulatory violations.

Logistical Functions to Support Constitutional Deadlines

Successful discharge of constitutional responsibilities is dependent upon the proper administration of functions such as budget oversight, monitoring performance metrics, public communication, internal and external training, contract management, special projects, reporting, strategic planning, and development of public educational materials.

Communication and Education

In the interest of transparency and in order to build public trust in this new program, the SMMR has designed its communication strategy to be both proactive and responsive. The SMMR uses the MMRP website to disseminate information and is working to build distribution lists to push categories of information to groups who have indicated interest in those topics. During this first year, DHSS also issued 24 news releases regarding developments in the implementation of Article XIV. DHSS also received and answered approximately 840 inquiries from the media related to the medical marijuana program from December 6, 2018, through December 5, 2019, and consistently responded in a timely manner.

In addition to strategic communication, the SMMR developed public education materials, such as tip sheets, registry user guides, and video tutorials to assist applicants and other stakeholders in understanding MMRP systems and processes. Also, a patient information booklet containing vital information such as qualifying medical conditions and qualified patient rights and responsibilities is in development and is scheduled for public release in early PY20. These printed items can be ordered free of charge from DHSS' warehouse.

Website

Timely and accurate dissemination of information to facilities, patients, physicians, and other stakeholders is facilitated through consistent updates to the SMMR's webpage. The webpage is a robust platform for receiving public comment on draft rules, published rules, special notices, detailed instructions for applicants regarding how to apply for licensure, patient fact sheets, MMRP Registry Portal user guides, frequently asked questions, required forms, tutorial videos, statistics, and additional resources. The webpage offers a compliance comment form for all constituents, including but not limited to, facilities, media, consultants, and law enforcement to post questions regarding medical marijuana compliance. Submitted comments are used to guide policy development, communication and public education. Additionally, facilities will be able to request variances, and the public will be able to submit complaints, by following a process posted on the website.

The webpage offers current, concise content and easy to navigate links making it an ideal avenue for channeling communication and outreach. Webpage analytics for the period of December 2018 through September 2019 are depicted in Figure 22, which indicates the number of unique page views to various MMRP webpages. Unique page views are a metric that aggregates page views during a user’s session and gives credit only once to each page viewed. The SMMR homepage is the second most frequently visited DHSS webpage based on unique views. The four webpages mentioned below were in the top 25 most frequently visited DHSS webpages. The analytics prove a positive public response to the design and delivery of communication mechanisms.

Figure 22: Number of Visits to SMMR Website, December 2018 – September 2019

December 2018 – September 2019	
Webpage	Unique Page Views
Home Page	271,903
Frequently Asked Questions	134,764
How to Apply	187,935
Rules	77,978

Collaboration with Special Project Workgroups

Implementation of Article XIV impacts multiple state agencies, and collaborating with these agencies has been a priority for the SMMR from the earliest days of the program. In addition to ongoing, direct collaboration, SMMR leads two formal workgroups focused on medical marijuana implementation, one of which includes representatives of numerous Missouri state agencies and the other, representatives of Missouri law enforcement entities. These workgroups will continue into PY20.

The SMMR also connects with interstate workgroups, such as the Cannabis Regulators Roundtable. This workgroup includes representatives from almost all of the states currently regulating marijuana in some form. The Roundtable brings together marijuana regulatory agencies with the intention of learning from other states’ experiences and assisting each other in crafting solutions to shared concerns.

Conclusion

Constitutional responsibilities were efficiently discharged in DHSS' implementation of Article XIV. Every constitutional milestone was reached on time or ahead of schedule through utilization of a comprehensive approach characterized at all times by extensive research, analysis, and stakeholder engagement. See Appendix A for a timeline of these activities.

The MMRP's initial focus, for PY19, was developing the SMMR's organizational model, recruiting and onboarding a large staff of qualified personnel, soliciting and procuring large scale IT solutions and external services, and meeting all deadlines for implementation. The execution of these tasks necessitated quickly building knowledge and expertise in regulation of medical marijuana industries, extensive and ongoing public outreach, efficient promulgation of an entire regulatory framework on an accelerated schedule, and developing hundreds of detailed processes for patient and facility application development and review. Implementation of Article XIV, with its breadth of responsibilities and aggressive timelines, was a monumental task. The MMRP is already being upheld as a model for others as new states enter this regulatory world and seek to understand what constitutes best practice in what is still a relatively new undertaking. DHSS is proud of the work that has been done to establish a safe and well-regulated medical marijuana industry for the State of Missouri. In the upcoming program year, the SMMR will focus on the last implementation phase, compliance and enforcement. This phase will require extensive collaboration to ensure facilities are fully educated on MMRP compliance activities and enforcement policies. The SMMR will continue with a broad-gauged, transparent approach to secure future program success. Stakeholder and public engagement will remain in the forefront as DHSS continues to build a program that provides safe and secure access to medical marijuana for qualifying Missouri patients through consistent regulation, enforcement, and education.

Appendix A: Implementation Dates and Constitutional Requirements

Implementation of Article XIV required meeting several mandatory deadlines throughout PY19. The list below provides specific dates constitutional requirements were met as well as the tasks needed to accomplish them.

- **January 1, 2019 through December 5, 2019:** The SMMR Director traveled across the state delivering presentations and participating in panel discussions at 112 separate events.
- **January 5, 2019:** Entities permitted to submit Pre-file Application along with non-refundable fees.
- **By January 2, 2019:** The SMMR Director and Deputy Director/Counsel were staffed.
- **January 10, 2019:** The SMMR issued a news release explaining its unique rule making process designed for public engagement.
- **February 6, 2019:** News release issued soliciting public comment in the rule making process.
- **By February 6, 2019:** Principal assistant and the Project Director positions were staffed.
- **February 13, 2019, through March 7, 2019:** The SMMR held five public forums around the state.
- **February 21, 2019, through May 20, 2019:** Draft rules posted to the website for public comment.
- **February 25, 2019:** Deloitte Consulting LLP contracted to assist with research, strategic priority framework, and organizational design of the new program.
- **April 5, 2019:** METRC LLC and sub-contractor, Complia, were contracted to deliver an online registry and seed to sale tracking system.
- **April 15, 2019, through April 25, 2019:** Advisory Committees met.
- **April 15-18, 2019:** METRC LLC/Complia contract award protested by MJ Freeway LLC and BiotrackTHC, delaying implementation of online patient registry system. The Missouri Office of Administration rejected both protests on May 20, 2019.
- **May 24, 2019:** Filed final Emergency and Proposed Rules, 19 CSR 30-95, with the Missouri Secretary of State's Office.
- **By May 31, 2019:** The SMMR expanded from four to 10 employees, allowing the program to staff its Operations Unit and Patient Services Unit and develop a call center.
- **June 4, 2019:** All sample facility and patient application forms and instructions posted to the website.
- **June 28, 2019:** The SMMR began accepting and processing patient, caregiver, and patient/caregiver cultivation applications six days earlier than the Constitutional requirement of July 4.
- **July 26, 2019:** Facility application video tutorials posted to website.
- **August 3, 2019, through August 19, 2019:** Facility application period to accept applications for licensing and certification of cultivation, infused-products manufacturing, dispensary, testing, seed-to-sale, and transportation facilities.
- **August 9, 2019:** Wise Health Solutions, Inc. was contracted to blind score facility license applications in accordance with Article XIV and associated rules.
- **By August 19, 2019:** The SMMR received over 2,270 facility applications.
- **October 29, 2019:** News release issued seeking public input on newly drafted Emergency Rule 19 CSR 30-95.028, Additional Licensing Procedures.
- **November 26, 2019:** DHSS filed Emergency Rule 19 CSR 30-95.028, Additional Licensing Procedures, to be effective December 5, 2019.
- **December 5, 2019:** News release issued advising of expected facility license issuances.
 - Laboratory Testing facilities – December 19, 2019.
 - Transportation facilities – December 23, 2019
 - Cultivation facilities – December 26, 2019
 - Infused-Products Manufacturing facilities – January 10, 2020
 - Dispensary facilities – January 24, 2020
 - Seed to Sale – January 31, 2020



Missouri Department of Health and Senior Services

Division of Regulation and Licensure

Section for Medical Marijuana Regulation

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