



MEDICAL MARIJUANA REGULATORY PROGRAM

2020 ANNUAL REPORT



[MedicalMarijuana.Mo.Gov](https://www.MedicalMarijuana.Mo.Gov)

History

Article XIV of the Missouri Constitution grants 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.

The Section for Medical Marijuana Regulation was created within DHSS to administer the Medical Marijuana Regulatory Program (MMRP). Per Article XIV, DHSS is required to annually submit a report to the Governor detailing the efficient discharge of its duties.

Reported activities herein are based on the MMRP program year (PY) of Dec. 6, 2019, through Dec. 5, 2020.



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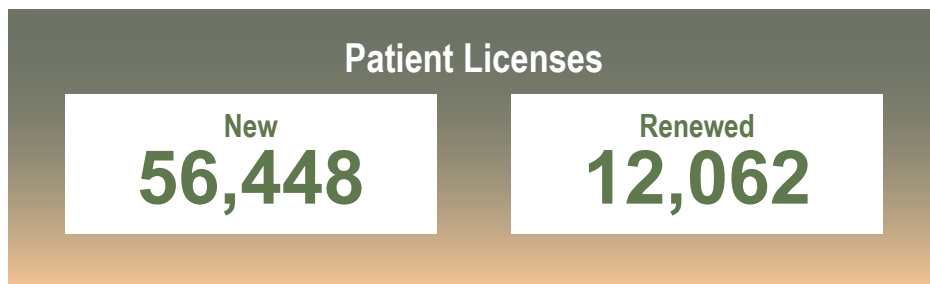
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Executive Summary

Key Achievements

During PY20, the DHSS began the last phase of program implementation, which was to approve facilities for operation and begin compliance activities in order to ensure safe product would be available for legal purchase. DHSS continues to process applications within the required deadlines.

- Cultivation, Manufacturing, Dispensary, Testing, and Transportation facility licenses were awarded;
- Facilities were approved to open for business;
- Medical marijuana laboratory testing started;
- Medical Marijuana sales began;
- Issued 56,448 new patient licenses and renewed 12,062 patient licenses.



What we do

Our 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.

What we aspire to be

Our Vision Statement

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

How we plan to get there

Our 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.



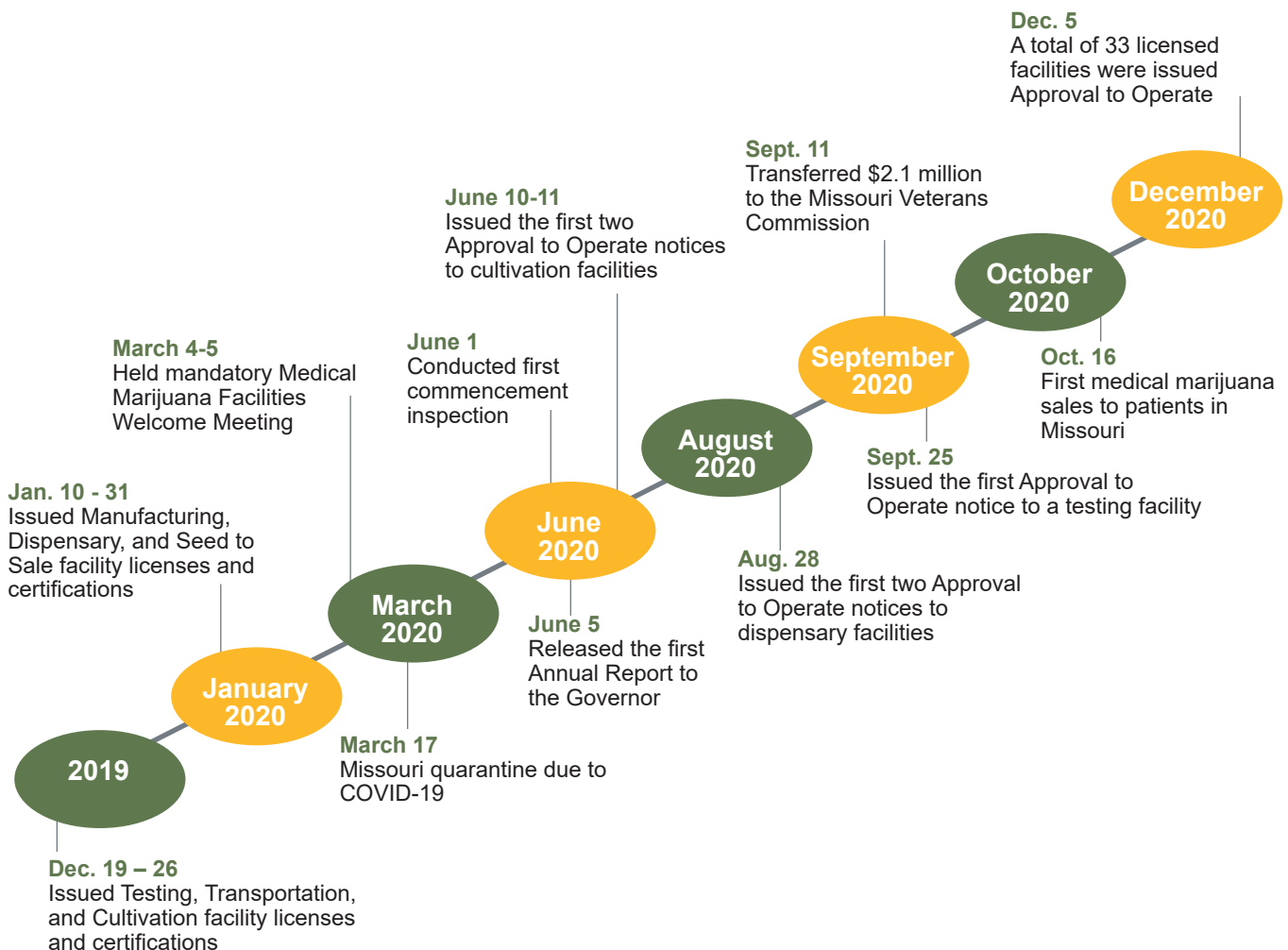
Introduction

This report is the annual accounting to the Governor regarding the efficient discharge of responsibilities granted to the DHSS by Article XIV, Section 1 of the Missouri Constitution and encompasses activities occurring during the PY of December 6, 2019 – December 5, 2020. These activities include:

- Promulgate rules;
- Receive fees for licenses and certifications;
- Approve or deny licenses and certifications; and
- Suspend, fine, restrict, or revoke licenses and certifications.

Licensure of medical marijuana facilities began during the first few weeks of PY20. In mid-March 2020, Missourians were asked to self-quarantine as the State responded to the coronavirus pandemic. Along with other state employees, DHSS transitioned its MMRP staff to remote work in order to continue implementation of the program without interruption. DHSS continued to provide quality customer service and ensured constitutional deadlines were met. While the coronavirus pandemic caused some of the newly licensed facilities to become operational less quickly as planned, DHSS experienced few operational challenges due to the pandemic and continued to work closely with all facilities to bring medical marijuana to the patients of Missouri.

Figure 1: Key Program Dates



State to State Medical Marijuana Program Comparisons

To assess implementation of the MMRP, DHSS reviewed publicly available data from 20 states that had passed medical marijuana laws since 2005: Arizona, Arkansas, Connecticut, Delaware, Illinois, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, and Utah.

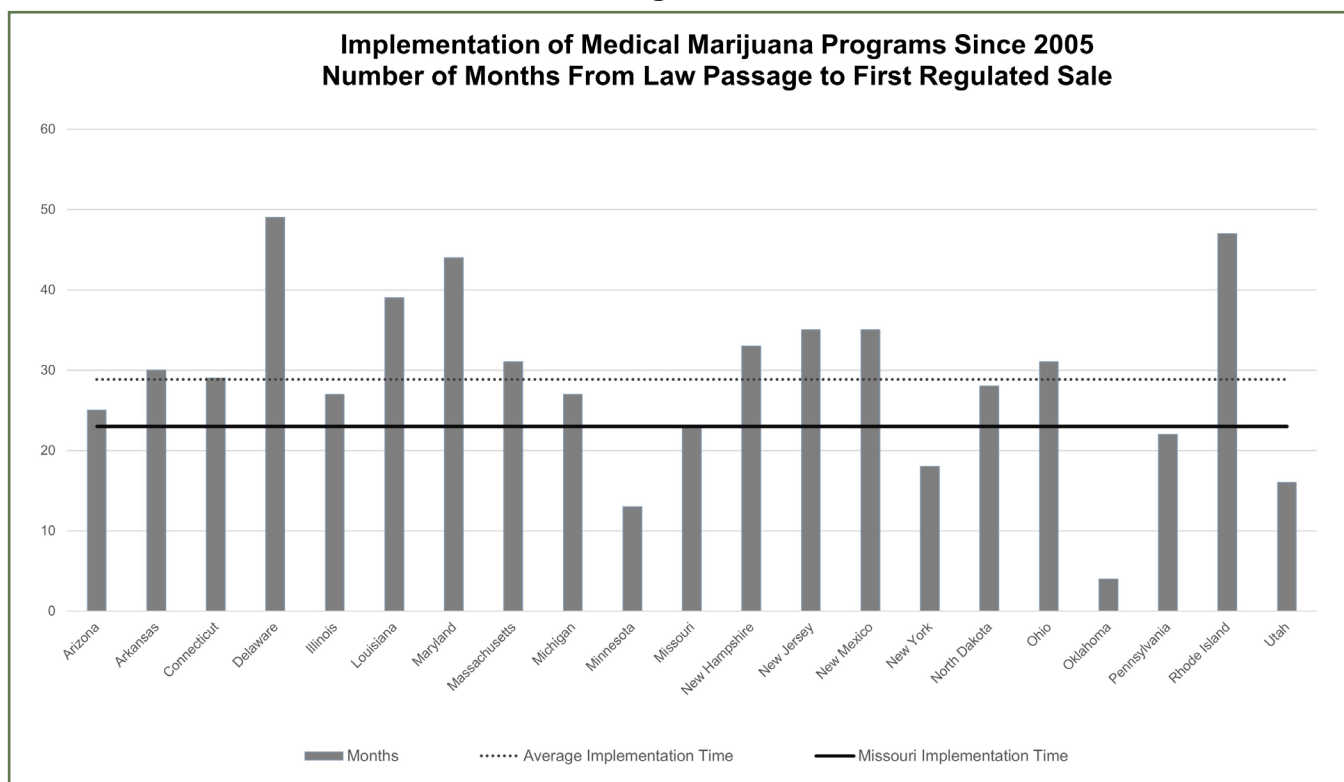
Medical marijuana laws and regulations vary from state to state, which presents challenges when making comparisons. Two distinctions were considered when selecting states for the analysis: how medical marijuana is defined and the date of the first regulated sale.

Article XIV allows for regulated facilities, regulated sales, and patient cultivation. Prior to 2005, few states contained provisions in their laws for regulated sales of medical marijuana as patients cultivated their own product. Thus, 2005 was the earliest year used to determine which states would be included in the analysis.¹

The Program Implementation Comparison Chart shows the number of months from law passage to date of first regulated sale of medical marijuana product. The average implementation time across all 21 states was 29 months. There were 11 (52 percent) states that implemented programs in 29 months or fewer: Arizona, Connecticut, Illinois, Michigan, Minnesota, Missouri, New York, North Dakota, Oklahoma, Pennsylvania, and Utah.

Missouri's implementation time was a little over 23 months. Only five states implemented programs in 22 or fewer months: Pennsylvania (22), New York (18), Utah (16), Minnesota (13), and Oklahoma (4).

Figure 2

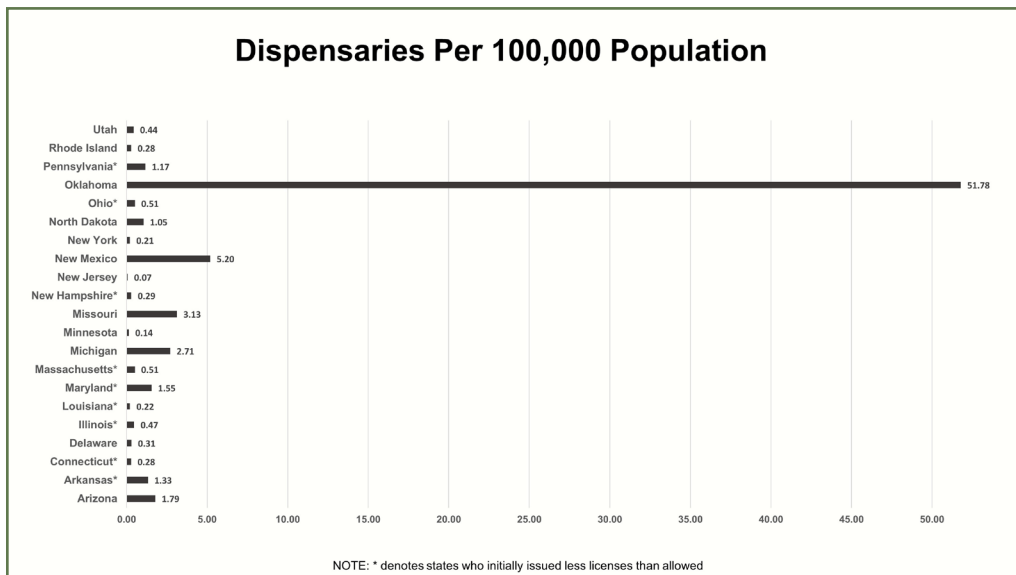


¹ While several states have amended their pre-2005 medical marijuana laws to include regulated facilities and sales, only Michigan and Rhode Island's post-2005 laws were amended to include regulated facilities and regulated sales. Michigan's 2008 medical marijuana law allowing for patient cultivation was amended in 2016 to allow for regulated facility sales, while Rhode Island's 2006 law was amended in June 2009. In both instances, the amended date was used as the date of law passage to calculate the implementation period. Virginia was not included in the analysis as their first sales did not occur until after the analysis was completed.

Figure 3 below depicts the number of licenses allowed in each state as a rate per 100,000 population. Utilization of this rate allowed differing state population sizes and differing number of awarded licenses to be compared. For states utilizing a limited license environment, the rate was calculated using the number of licenses allowed. In those states with an unlimited environment, the rate was calculated using the number of licenses awarded at the time of the analysis, which was August 2020. The analysis found:

- 17 (85 percent) of the cohort states utilized a limited license environment;
- Eight (40 percent) states initially awarded less than the maximum number of licenses allowed in their license environment; and
- Oklahoma had the most licenses awarded with a rate of 51.78 dispensaries for every 100,000 citizens. New Mexico had the second highest rate of 5.20 followed by Missouri with a rate of 3.13.

Figure 3



State	2019 Population Estimates	Dispensaries Allowed in Licensing Environment
Arizona	7,278,717	130
Arkansas	3,017,804	40
Connecticut	3,565,287	10
Delaware	973,764	3
Illinois	12,671,821	60
Louisiana	4,648,794	10
Maryland	6,045,680	94
Massachusetts	1,344,212	35
Michigan	9,986,857	Unlimited
Minnesota	5,639,632	8
Missouri	6,137,428	192
New Hampshire	1,359,711	4
New Jersey	8,882,190	6
New Mexico	2,096,829	Unlimited
New York	19,453,561	40
North Dakota	762,062	8
Ohio	11,689,100	60
Oklahoma	3,956,971	Unlimited
Pennsylvania	12,801,989	150
Rhode Island	1,059,361	3
Utah	3,205,958	14

Promulgate Rules

Article XIV grants DHSS the authority and responsibility to promulgate rules necessary for the proper regulation of qualified patient access to medical marijuana. The initial proposed rules governing the persons and entities regulated by DHSS became effective in January 2020 with very few changes from the emergency rules which were filed in May 2019. The rulemaking process for this set of rules was detailed in the MMRP's PY19 Annual Report to the Governor.

During PY20 DHSS filed one new rule, considered rule changes to three rules, and filed one proposed amended rule. DHSS continued the adopted process of engaging the public early in its consideration of whether to promulgate revisions to its rules by posting a link on February 25, 2020, to a Suggestions Form on its Draft Rules webpage and issuing a press release March 3, 2020. This process provided the public months to view and comment on draft changes prior to DHSS filing proposed amendments with the Missouri Secretary of State's Office and the subsequent formal 30-day public comment period.

Public Forums and Public Comments

During 2019, national concern was raised regarding an e-cigarette/vaping-associated lung injury (EVALI) outbreak. Subsequent investigations linked over three-quarters of EVALI cases to tetrahydrocannabinol (THC) products. On January 9, 2020, DHSS held a public forum in Jefferson City on medical marijuana vaping. Additionally, DHSS posted a Suggestions Form on its website. In total, DHSS received 46 suggestions between December 17, 2019, and January 13, 2020, regarding regulation of vaping products containing THC. Almost all feedback received advocated for access to safe THC vaping products.

- DHSS solicited and received public feedback on draft revisions to 19 CSR 30-95.110 Physicians, 19 CSR 30-95.080 Dispensary Facilities, and 19 CSR 30-95.010 Definitions. On February 21, 2020, DHSS posted proposed changes to 19 CSR 30-95.110 Physicians and re-instated the Suggestions Form to solicit public feedback. There were seven suggestions received.
- On May 18, 2020, DHSS posted proposed changes to 19 CSR 30-95.080 Dispensary Facilities to its website and accepted public feedback until June 18, 2020. There were 279 suggestions received. The draft revisions for this rule included changes related to medical marijuana vaping based on feedback received from the EVALI public forum.
- On June 4, 2020, DHSS posted proposed changes to 19 CSR 30-95.010 Definitions and accepted public feedback until June 18, 2020. Only three suggestions were received.

Filed Rules and Rule Amendments

In July 2020, a new proposed rule became effective, with its emergency rule counterpart already effective December 2019. This rule, 19 CSR 30-95.028 Additional Licensing Procedures, was promulgated to explain how licensees would accept licenses and to establish that certain denied applicants would be conditionally denied for a period of time in case a license became available.

Proposed amendments to 19 CSR 30-95.110 Physicians were filed with the Missouri Secretary of State for publication in the July 1, 2020, volume of the *Missouri Register*. The amendment added Section (3) Physician Investigations to the existing Physicians rule. Section (3) allows DHSS to investigate physician complaints pertaining to Article XIV and associated rules and take action to refer findings to the Missouri State Board of Registration for the Healing Arts as well as to law enforcement. Section (3) also establishes processes through which DHSS may refuse to accept certifications from a physician for a length of time based upon the following criteria:

- Whether the physician acted recklessly or knowingly in violating a rule or law impacting the medical marijuana program;
- The degree of imminent danger to the health of a qualifying patient the physician's actions caused;
- The degree of falsification of a physician certification;
- Whether DHSS has previously received substantiated complaints against the physician; and
- Any aggravating circumstances.

During the formal 30-day public comment period for this proposed amendment, no comments were received, and no revisions were made to what was proposed.

Missouri Veterans' Health and Care Fund

The Missouri Veterans' Health and Care Fund ("Veterans' Fund") was established for receiving all fees and taxes collected pursuant to Article XIV. In addition to licensing fees collected by DHSS, Article XIV requires a four percent tax on the retail sale of medical marijuana to be submitted to the Missouri Department of Revenue (DOR). DOR is allowed to retain up to five percent of the collected tax for its administration with the remaining amounts to be deposited into the Veterans' Fund. The first sales of medical marijuana occurred on October 16, 2020, and the first scheduled date of tax submission was November 2, 2020.

Article XIV also requires that DHSS use the Veterans' Fund to carry out its responsibilities in implementing the MMRP. Any remaining funds are to be transferred to the Missouri Veterans Commission. FY21 was the first fiscal year in which a transfer of funds to the Missouri Veterans Commission was effectuated by the legislature through the appropriation process.

Administration of the MMRP

The MMRP is a self-funded program, meaning DHSS' operating costs to administer the MMRP are fully funded through fees. DHSS operating costs include fixed expenditures for personnel and variable expenditures for costs associated with maintaining the license registry and the medical marijuana track and trace system; supplies and equipment; travel to inspect facilities; and costs associated with appeals of licensure denials and revocations. The legislature appropriates a budget according to the state fiscal year cycle, which runs July 1 through June 30. The table below details the legislatively appropriated MMRP budget and the amount DHSS expended each fiscal year.

Figure 4: Appropriated Budget and Expenditure for Fiscal Years 2019 - 2021

Fiscal Year (July 1 – June 30)	MMRP Appropriated Budget	MMRP Expended Budget
FY19	\$3,161,975	\$585,014
FY20	\$13,311,557	\$6,277,430
FY21	\$13,543,316	\$3,139,650*

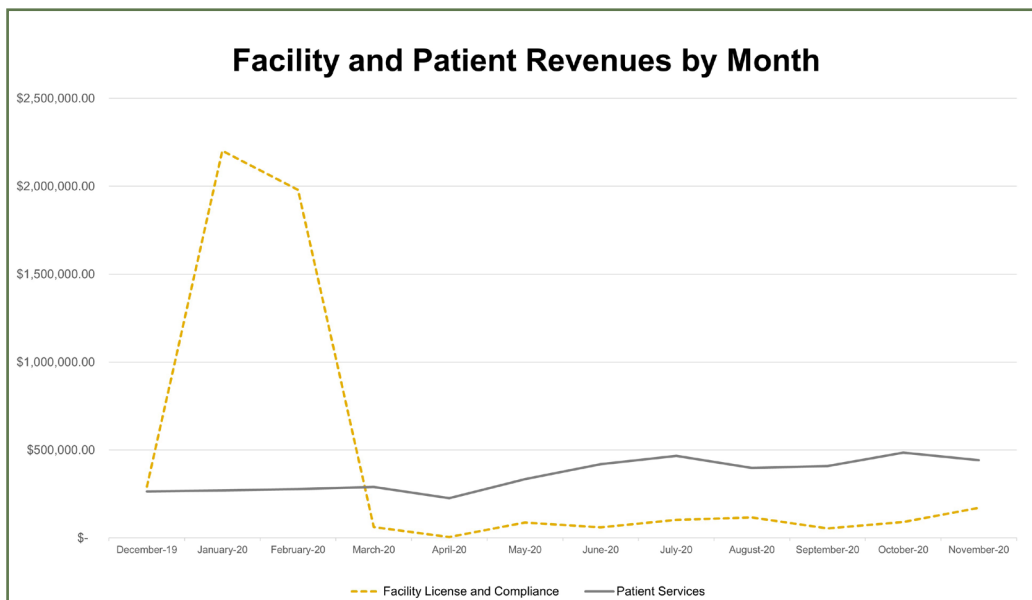
* Amount between July 1, 2020 and December 5, 2020

Program Revenue and Fee Structure

Program Revenue

While the fiscal year begins July 1, the substantial portion of revenues originate during December and January in the form of facility annual fees, as seen in the Facility and Patient Services Revenues by Month graph below.

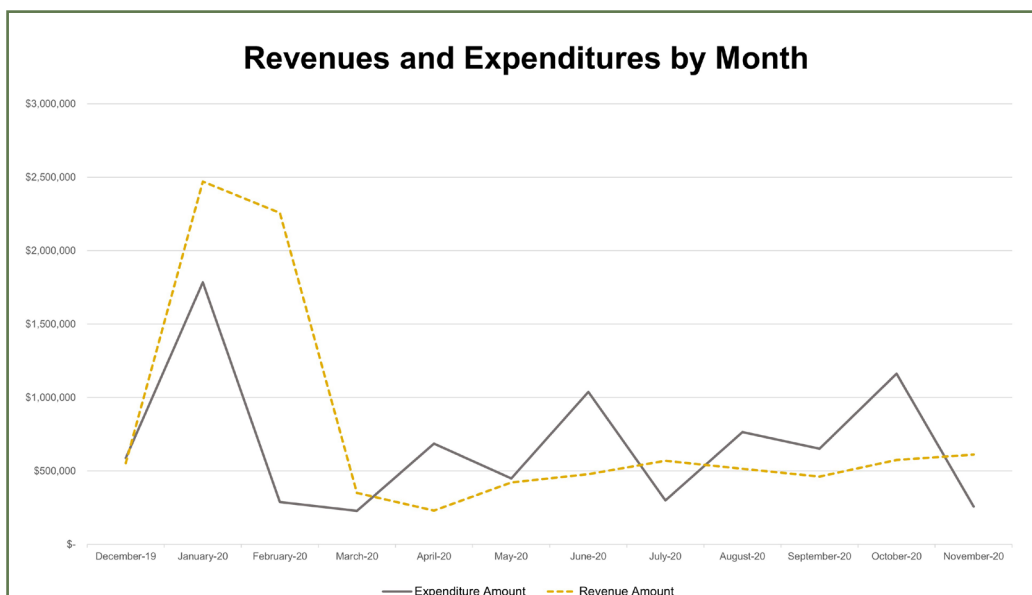
Figure 5



This uneven revenue flow results in a need to maintain enough of a reserve balance in the Veterans' Fund on June 30th to cover MMRP's estimated operating expenses for the first six months of the next state fiscal year of July through December.

In the Revenues and Expenditures by Month graph below, there were six months when the MMRP monthly expenditures exceeded the monthly collected revenues.

Figure 6



Fees Structure

Per Article XIV Section 1, certain application fees and licenses are “...increased or decreased each year by the percentage of 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.” This language has been published with the fee schedules since May 2019. Annual fee adjustments are effective July 1 to align with the MMRP’s budget cycle and Missouri’s state fiscal year.

The Consumer Price Index rose 2.3 percent from 2018 to 2019. There is no provision in Article XIV allowing MMRP to waive annual adjustment of fees, so the 2.3 percent increase was applied to licensure fees for July 1, 2020 – June 30, 2021. New fee schedules were posted to the website on May 11, 2020. The Patient, Caregiver, and Patient Cultivator Fee Chart and Facilities Fee Chart below illustrate the initial and current application fees.

Figure 7

Patient, Caregiver, and Patient Cultivator Fee Chart

Fee Type	Application (12/6/2019 - 6/30/2020)	Renewal (12/6/2019 - 6/30/2020)	Application (7/1/2020 - 6/30/2021)	Renewal (7/1/2020 - 6/30/2021)
Patient	\$25	\$25	\$25.58	\$25.58
Caregiver	\$25	\$25	\$25.58	\$25.58
Patient Cultivator	\$100	\$100	\$102.30	\$102.30

Facilities Fee Chart

Type	New Application (12/6/2019 - 6/30/2020)	New Application (7/1/2020 - 6/30/2021)	Annual (12/6/2019 - 6/30/2020)	Annual (7/1/2020 - 6/30/2021)
Change Request Fee	\$2,000.00	\$2,046.00	NA	NA
Cultivation Facility	NA	NA	\$25,000.00	\$25,575.00
Dispensary Facility	NA	NA	\$10,000.00	\$10,230.00
Facility Agent	\$75.00	\$76.73	NA	NA
Laboratory Testing	NA	NA	\$5,000.00	\$5,000.00
Manufacturing Facility	NA	NA	\$10,000.00	\$10,230.00
Seed to Sale	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00
Transportation	\$5,000.00	\$5,000.00	\$5,000.00	\$5,000.00

Per Article XIV, facility application fees are non-refundable. All other fees are refundable, and most refunds occur due to overpayments. Patient, caregiver, and/or patient cultivator application fee overpayments occur when applicants select the wrong payment category in the payment portal or double pay for patient cultivation when both the patient and the caregiver submit a patient cultivation application. Refunds at a prorated amount were granted in PY20 to patients who were affected by fraudulent physician certifications discovered during a MMRP investigation. Most facility annual fees and change request refunds occurred due to overpayment made as facilities learned the process for assessing and submitting payments.

Licenses and Certifications

Patient and Caregiver Licensure

On July 6, 2020, just eight days after the one year anniversary for accepting patient applications, the MMRP received its 60,000th patient application and had issued over 54,000 patient licenses. The 2019 *Missouri's Medical Marijuana Market: An Economic Analysis of Consumers, Producers, and Sellers* considered patient adoption as a percent of population and found that states had, on average, an adoption of rate of 0.7 percent. Missouri's first year adoption rate was 0.9 percent. For perspective, Arizona's first year adoption rate was 0.5 percent according to the 2019 analysis.

Figure 8

Program Year Summary: Submitted and Issued Counts		
Type	Submissions (Number)	Issued (Number)
New Patient	64,485	56,448
Patient Renewal	14,050	12,062
New Caregiver	2,479	2,019
Caregiver Renewal	312	255
New Patient Cultivation	14,633	8,703
Patient Cultivation Renewal	6,157	5,486
Agent Identification Card	1,005	934

Note: The first applications for agent identification cards and card renewals were received in April 2020.

During PY20, DHSS received over 103,000 patient and caregiver applications. Article XIV and associated rules require DHSS approve or deny applications for patient and caregiver identification cards (also referred to as "licenses" or "cards") within 30 days of receiving a complete application, and applications for facility agent ID must be approved or denied within 14 days of receiving a complete application. On average, DHSS processes patient applications within 13 days, caregiver applications within 14 days, and agent ID applications within two days.

Average monthly application submissions: 5,374 new patient, 1,091 patient cultivators, 1,982 patient renewals, 207 new caregivers, 128 caregiver cultivators, 52 caregiver renewals, and 112 agent IDs for a total of 8,946. At the close of PY20, there were 69,397 active patient identification cards. Approximately 90 percent of new patient and patient renewal applications are issued a card, over 75 percent of new caregiver and caregiver renewal applications are issued a card, while approximately 95 percent of agent applications are issued a card.

Figure 9

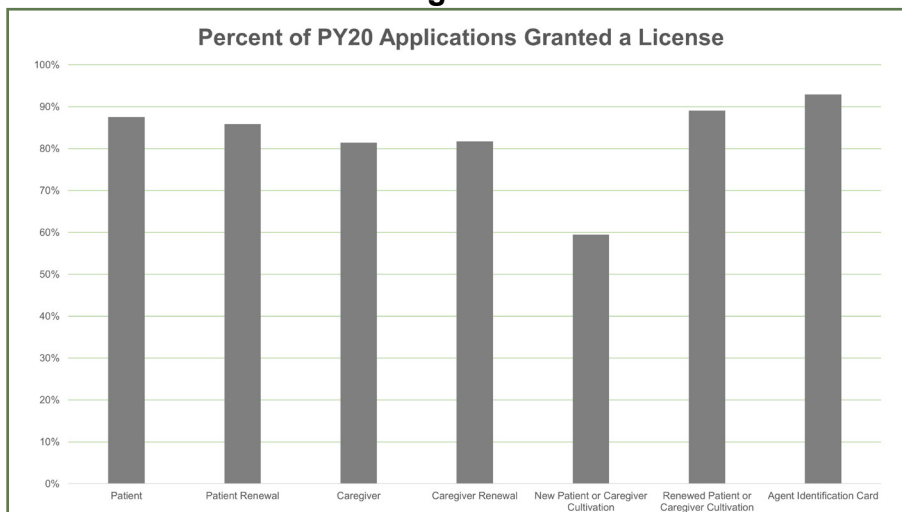


Figure 10

Licenses in Active Status				
Month	Patient	Caregiver	Patient Cultivation	Agent ID
2019-12	26,950	714	8,670	
2020-01	31,292	865	10,025	
2020-02	36,135	1,017	11,204	
2020-03	41,874	1,194	12,504	
2020-04	46,004	1,361	13,947	12
2020-05	50,703	1,500	15,262	38
2020-06	54,111	1,582	16,324	60
2020-07	56,643	1,692	16,720	157
2020-08	59,730	1,811	17,669	206
2020-09	63,014	1,961	18,582	361
2020-10	64,980	2,070	19,096	589
2020-11	68,222	2,117	19,637	883

NOTE: Counts for active licenses are captured on or near the last day of the month and are current as of the date of capture.

Figure 11

Licenses Issued						
Month	New Patient	Patient Renewals	New Caregiver	Caregiver Renewals	Patient Cultivation	Agent ID
2019-12	5,199		185		1,740	
2020-01	4,351		156		1,456	
2020-02	4,847		156		1,389	
2020-03	5,739		177		1,701	
2020-04	4,130		180		1,474	12
2020-05	4,716	199	149		1,683	26
2020-06	3,932	1,046	123	15	1,894	22
2020-07	4,443	1,919	156	34	2,348	97
2020-08	5,404	2,079	180	63	2,687	49
2020-09	4,712	1,981	195	43	2,429	155
2020-10	4,582	2,202	193	39	2,320	228
2020-11	6,159	2,211	162	47	2,223	295

Patients may renew their card up to 60 days prior to expiration. The first patient renewals were received in April 2020. At the close of PY20, DHSS received 14,304 renewal applications. A total of 12,054 (84 percent) were approved for renewal and 1,716 (12 percent) were still in the application process. It is important to note that retention of active patient cards is not a program goal as many factors influence surrender or non-renewal of a card such as death, improved condition, or pursuit of a different treatment option. The program has a current retention rate of 49.74 percent.

Defining Licensure Data

Issued patient card data is a static number and refers to those licenses issued to patients. It includes all card status designations – those that are active, expired, and deactivated.

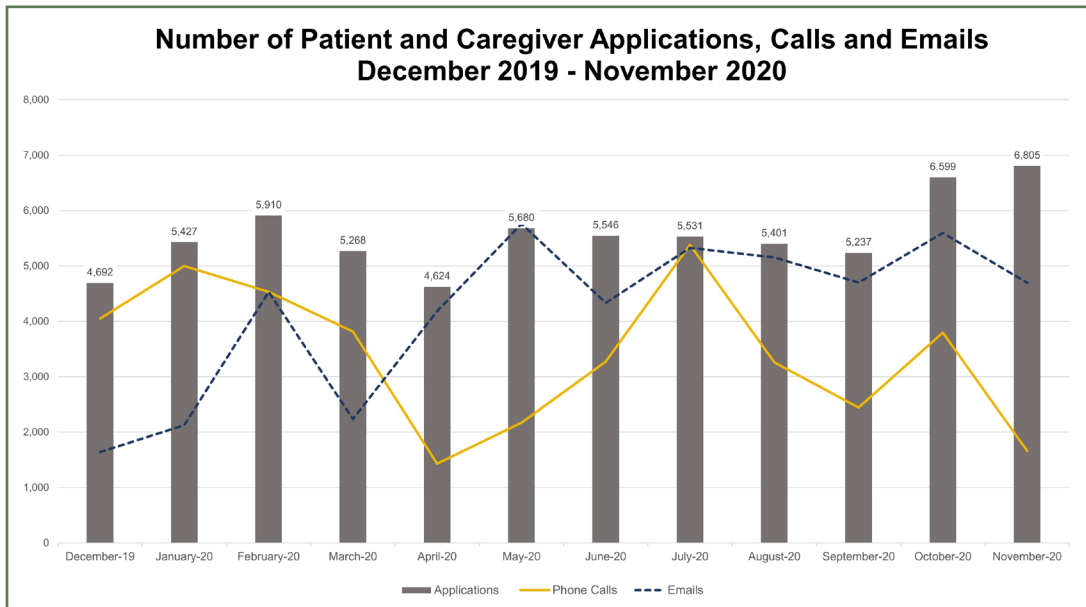
In comparison, active patient data is a fluid, time-specific number which changes every time the status of a patient record changes. In the PY19 Annual Report, active counts were referred to as “Approved”. Retention considers whether a distinct card number issued during the previous year was re-issued during the current program year.

Applications, Calls, and Email Processing

From December 2019 through November 2020, Patient Services received and responded to an average of 5,560 emails monthly. Patient Services continues to process applications according to constitutionally prescribed deadlines while simultaneously responding to a high volume of calls and email inquiries. DHSS suspended the toll-free Patient Services' customer call line in March 2020 due to the State's response to the coronavirus pandemic and reactivated the toll-free line on June 8, 2020. Patient Services began processing agent ID applications in April 2020, and patient and caregiver renewal applications in May 2020.

The figure below highlights the volume of applications, calls, and emails received by month from December 1, 2020 through November 30, 2020.

Figure 12



Patient Services began receiving and processing applications for patient and caregiver cards and patient cultivation cards on June 28, 2019. The figure below illustrates a comparison of active licenses in PY19 and PY20. PY20 active license numbers includes retention of active licenses through the renewal process that began on June 28, 2020.

Figure 13

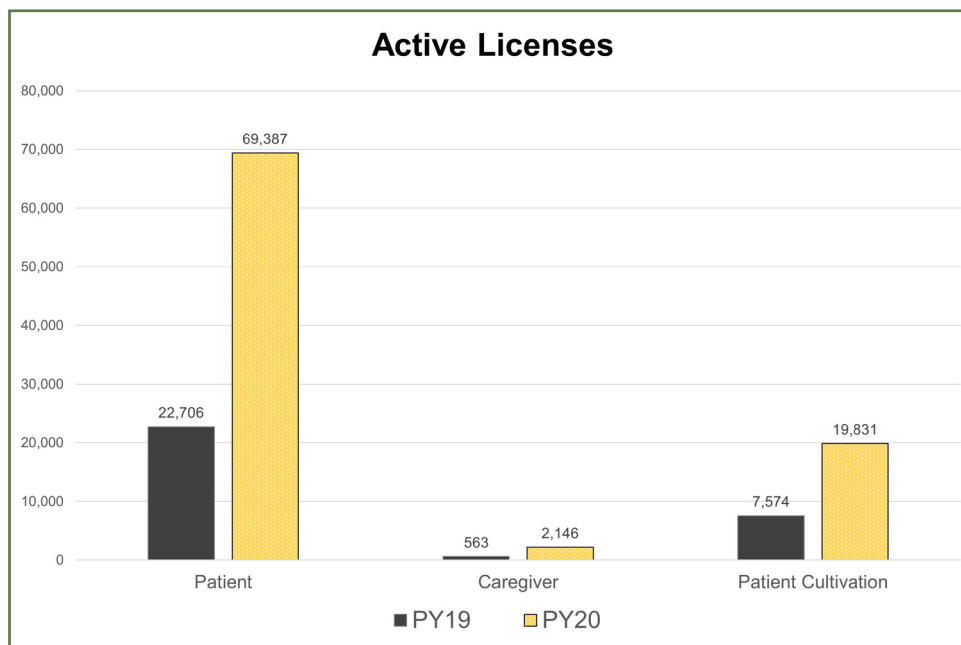


Figure 14

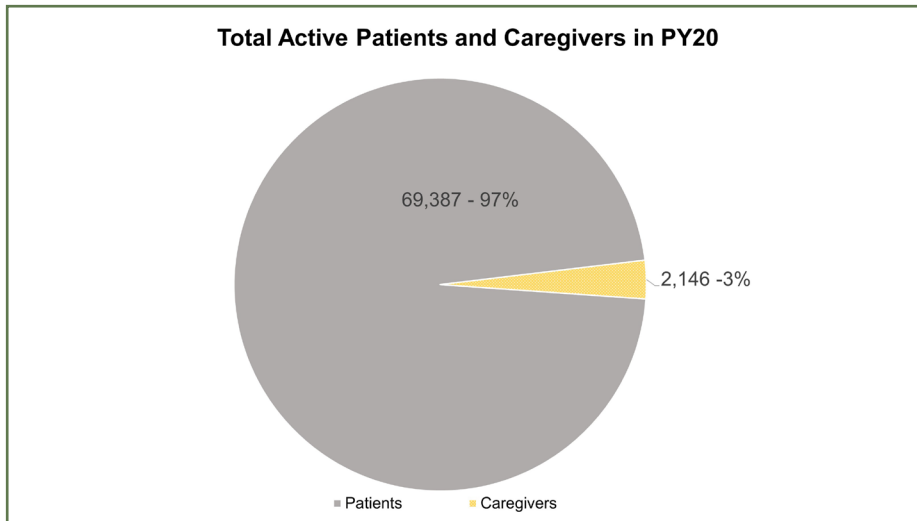
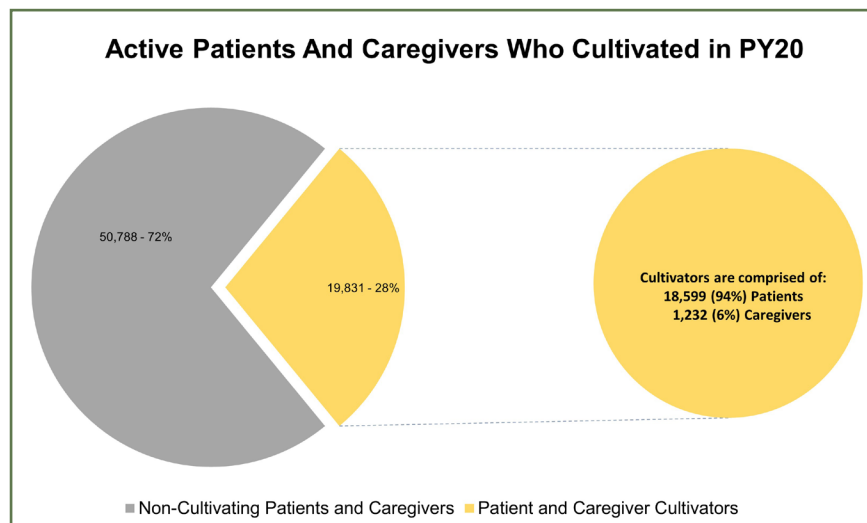


Figure 15



The figure below depicts active qualifying patients by condition for PY20. Appendix B of this report provides a list of individual conditions for each category in the graph.

Figure 16

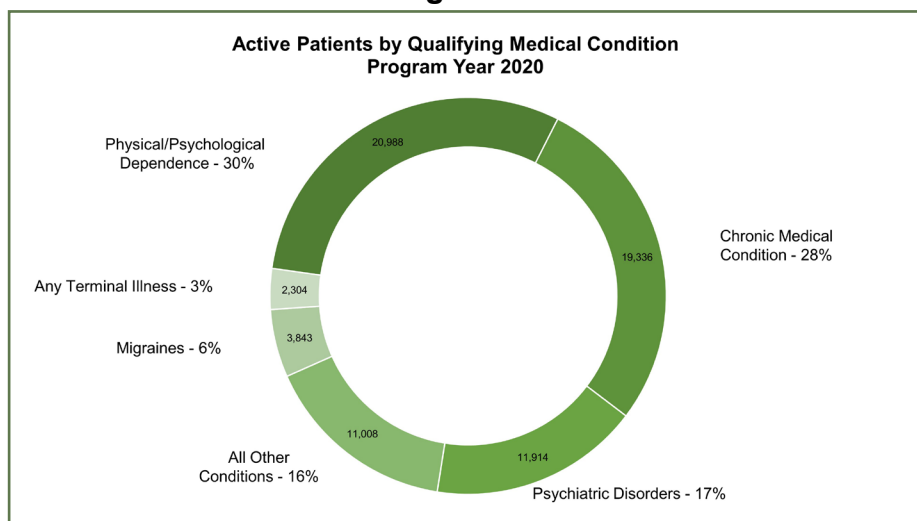


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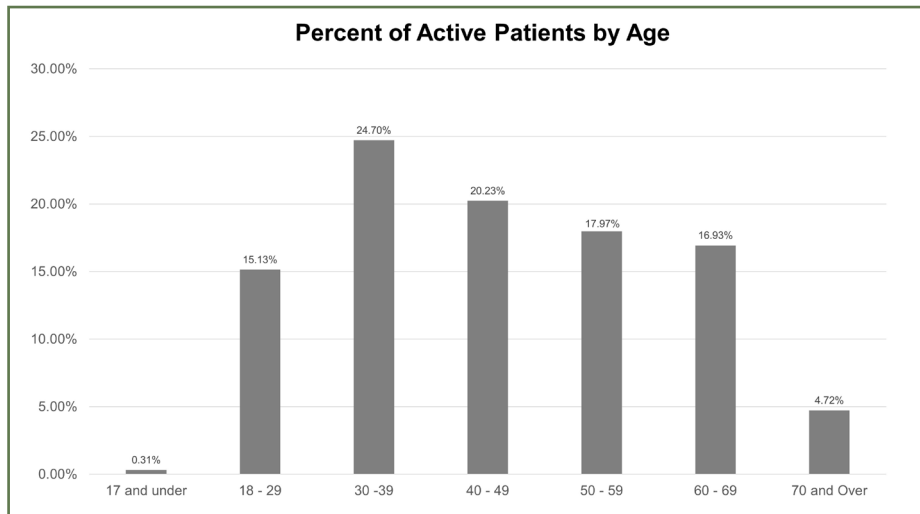
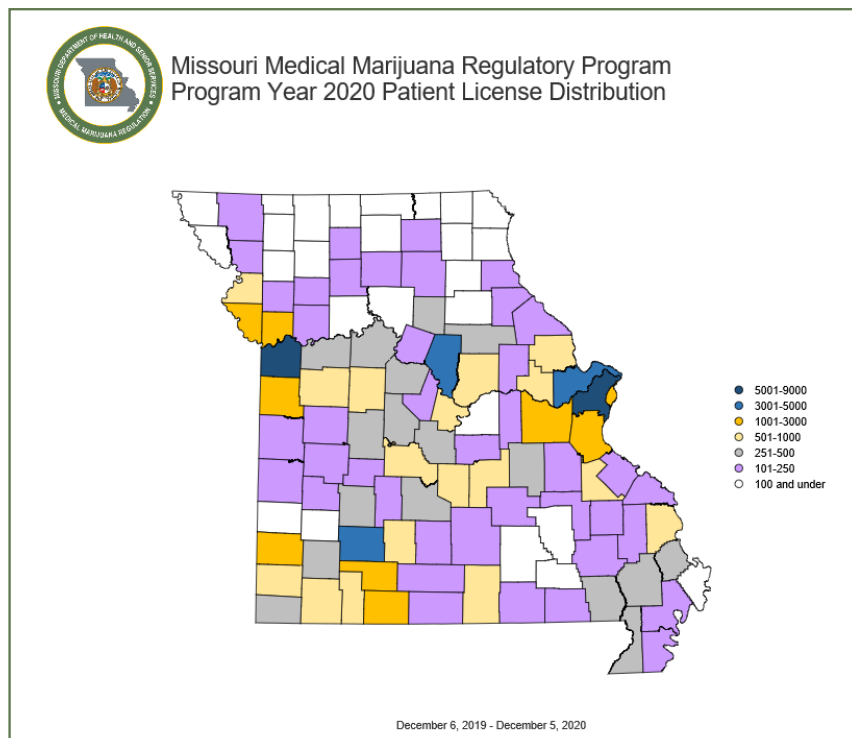


Figure 18

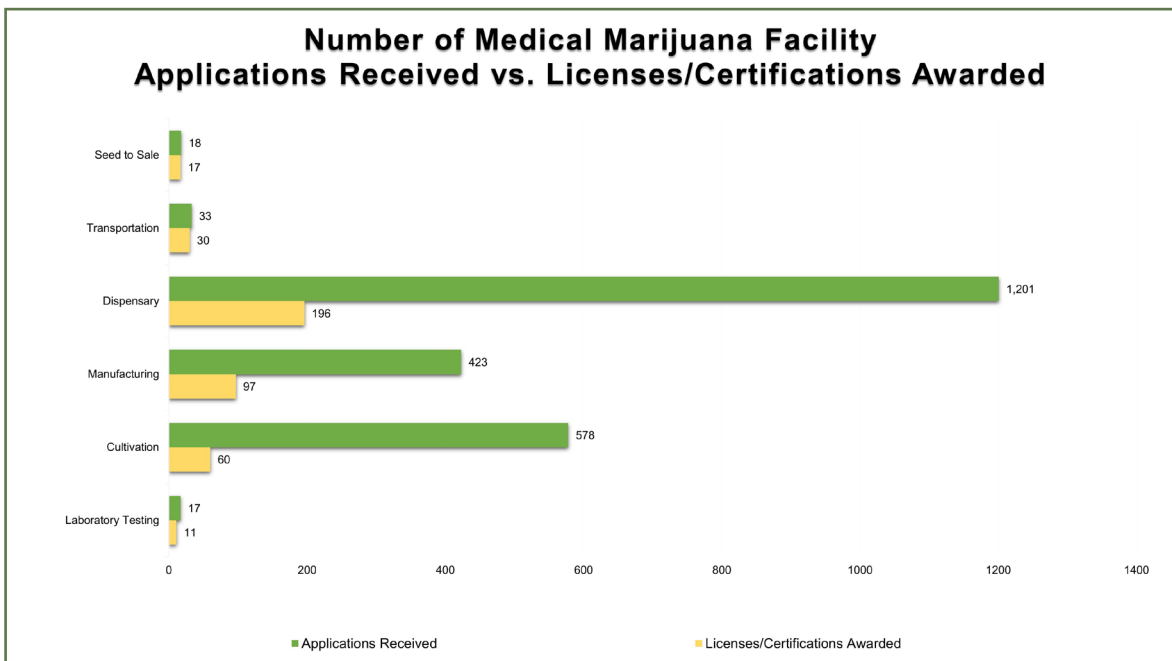


Facility Licensure

Beginning in December 2019, DHSS issued licenses to all medical marijuana facility types after finalizing application review, scoring, and ranking of more than 2,000 applications. Facilities were notified of their application status on the following dates:

- Laboratory Testing facilities – December 19, 2019 – 10 certifications issued
- Transportation facilities – December 23, 2019 – 21 certifications issued
- Cultivation facilities – December 26, 2019 – 60 licenses issued
- Infused-Products Manufacturing facilities – January 10, 2020 – 86 licenses issued
- Dispensary facilities – January 23, 2020 – 192 licenses issued
- Seed to Sale – January 31, 2020 – five certifications issued

Figure 19



Data as of December 4, 2020

Note 1: The figures for transportation facilities and seed to sale vendors are subject to change, as both application types are open continuously for submission. The application period for all other facility types is closed.

Note 2: The figure for dispensary licenses awarded included four licenses that have since been deactivated. There were 192 active dispensary facilities.

Note 3: The figure for transportation certifications awarded included seven certifications that have since been deactivated. There were 22 active transportation facilities, and one pending license acceptance/payment.

Note 4: The figure for manufacturing licenses included ten licenses that have since been deactivated and merged into one license and one license that has since been surrendered; new licenses were awarded to replace the licenses that were deactivated or surrendered. There were 85 active manufacturing facilities, and one pending license acceptance/payment.

Note 5: The figure for seed to sale certifications awarded included one certification that was in the process being surrendered.

Following License Award

DHSS required facilities notify DHSS whether they accepted the license or certification. After acceptance, the licensee submitted their annual fee. Per rule, facilities had one year from their license issuance date to pass a Commencement Inspection or request a variance to extend their operational deadline.

DHSS began working with the statewide track and trace system vendor, Metrc, in late December 2019 to establish Missouri specific configurations and begin system implementation. Missouri specific configurations were complete in mid-March, and the system was fully implemented and live on May 1, 2020. All phases of the medical marijuana supply chain are tracked through the Metrc track and trace system. The system is available continuously and tracks medical marijuana from either the seed or immature plant stage until the marijuana is sold to a qualifying patient or primary caregiver. The track and trace system contains real time information for each medical marijuana facility approved to operate.

Between January and February, DHSS conducted a mandatory survey of all facility types, with the exception of Seed to Sale. The purpose of the survey was to assess facility readiness and aid DHSS in preparing and prioritizing policy and procedure development. Facilities answered questions regarding banking services, any planned changes to the facility, state and local permits, and Commencement Inspection readiness.

Survey results provided the following insights:

- 75 percent of respondents had secured banking services.
- Licensees indicated they may have a total of 340 business change requests to submit.
 - 87 respondents indicated they may submit an ownership change request for a 10 percent or more change to the ownership interests of the facility.
 - Seven respondents indicated they may submit a transfer change request to assign, sell, lease, sublicense or otherwise transfer its license or certification to another entity.
 - 88 respondents indicated they may submit a change request to share space with another facility at a single location.
 - 108 respondents indicated they may submit a material deviation change request that makes a change that impacts the facility's ability to fulfill a key aspect of its proposed operations.
 - 50 respondents indicated they may submit a change request to site a warehouse at a location other than the approved location of the facility.
- 82 percent of respondents had not received all state and local permits applicable to their facility type.
- 34 percent of respondents indicated that they would be ready for a Commencement Inspection between January and June.

DHSS held a mandatory Missouri Medical Marijuana Facilities Welcome Meeting on March 4 for cultivation, manufacturing, laboratory testing, and transportation facilities and on March 5 for dispensary facilities and seed to sale vendors. Each facility was required to attend the meetings based on their licensed facility type and were allowed to send up to two representatives per license. The purpose of the meeting was to meet DHSS Facility Licensing and Compliance staff, learn about MMRP policies and procedures, and network with other licensees. Other state agencies including the Departments of Agriculture, Labor and Industrial Relations, Natural Resources, Public Safety, and Revenue attended the meetings to provide the State's new industry with information on their respective regulations and requirements as well as information to help new businesses operate in Missouri. More than 300 individuals participated in the welcome meetings, establishing a significant first step toward successful commencement and regulatory compliance.

DHSS held roundtable conference calls in March and April with laboratory testing and transportation facilities. The roundtables provided facilities with the opportunity to hold an open discussion with DHSS to review questions and concerns, and for testing facilities to discuss test standards and ISO accreditation. The conference calls were well attended by representatives from each facility group.

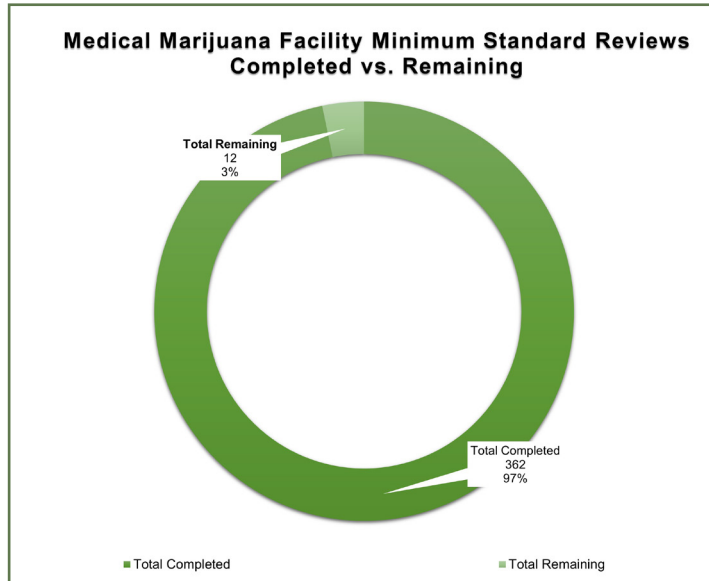
The first regulatory priority for DHSS was to verify that each licensee was in compliance with the minimum standards for licensure outlined in Article XIV and 19 CSR 30-95. The minimum standards include:

- The entity is authorized to operate as a business in Missouri;
- The entity is majority owned by natural persons who have been residents of Missouri for at least one year;
- The entity is not under substantially common control as another entity or combination of other entities in violation of 19 CSR 30-95.040(3)(C)-(D);
- The entity is not within 1,000 feet of an existing school, daycare, or church, or a local government's less restrictive requirements;
- The entity can comply with any local government zoning laws; and
- The entity will not be owned in whole or in part by, or have as an officer, director, board member, or manager, an individual with a disqualifying felony offense.

Immediately after licenses were issued, DHSS began the process to review the minimum standards for all licensed and certified facilities. During the Minimum Standards review, facilities were required to work with DHSS to provide all documentation necessary to confirm they were truthful and transparent regarding minimum standards in their application for licensure. Documentation required included property ownership records, financial records, executed leases, management agreements, ownership verification documents, and other contracts.

The average processing time for a thorough Minimum Standards review was approximately 25 hours once all documentation was received by licensees. As of December 4, 2020, 267 Minimum Standards reviews had been completed, two of which were for facilities that later surrendered their license. The first chart below illustrates the total number of Minimum Standards reviews required vs. complete.

Figure 20



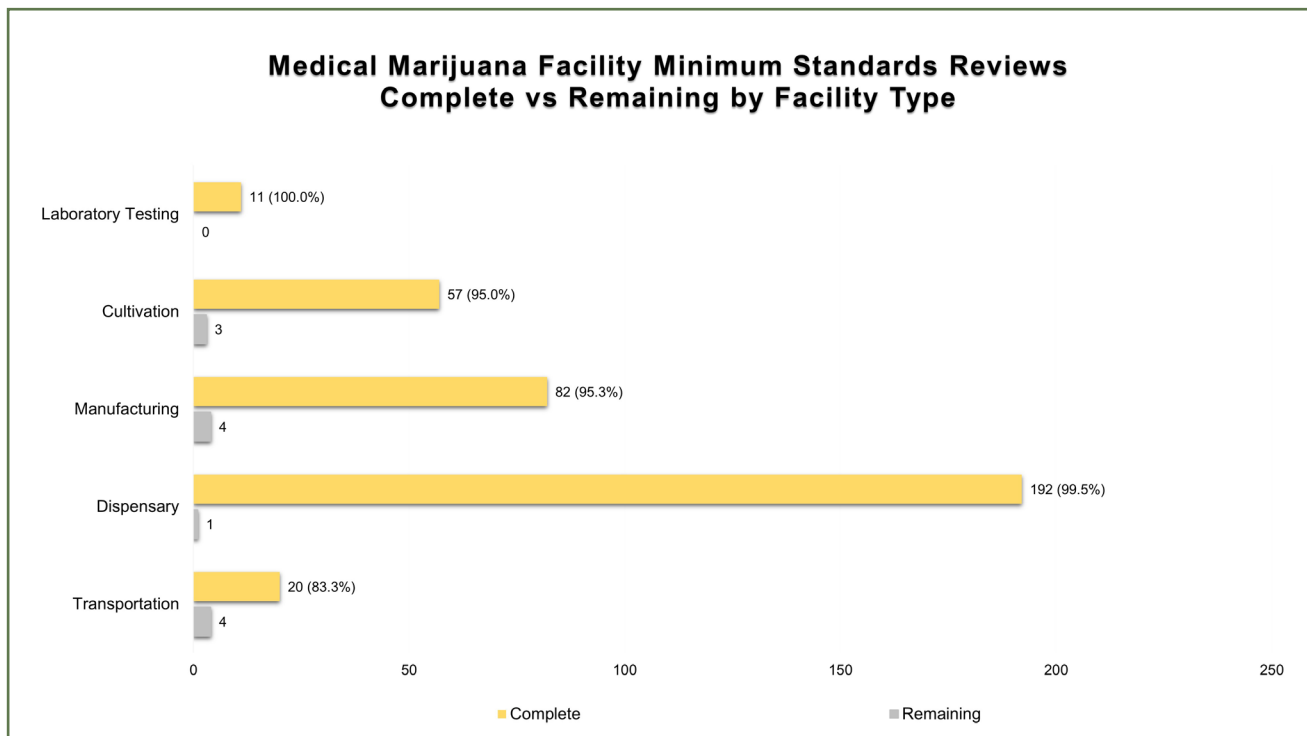
Data as of December 4, 2020

Note 1: as of December 4, 2020, the total number of active licensed/certified facilities requiring a Minimum Standards Review is 372. This figure is subject to change in the event additional certifications are awarded for transportation facilities, which are continuously open for application submission.

Note 2: The figure for total completed Minimum Standards Reviews includes two reviews that were completed for a facility license or certification that has since been deactivated.

The next figure provides a further breakdown of the number of Minimum Standards reviews required vs complete by facility type.

Figure 21



Once DHSS completed a facility's Minimum Standards review, they were authorized to either request a Business Change Request if any changes were necessary that required DHSS approval or to proceed through the Commencement Inspection process to become operational. The requirements for a Business Change Request can be found in 19 CSR 30-95.040(4)(C), which states that all licensed or certified cultivation, dispensary, manufacturing, testing, and transportation facilities must seek and obtain DHSS approval before they may:

- Assign, sell, give, lease, sublicense, or otherwise transfer its license to any other entity;
- Make ownership changes great than 10 percent;
- Materially deviate from the proposed physical design, including location;
- Combine licensed facilities at a single location; or
- Construct offsite warehouses.

During the program year, DHSS received 227 business change requests. By the end of the program year, 128 change requests had been processed and 99 were in the review process.

Facilities that were ready for a Commencement Inspection were asked to request their inspection a month prior to when they would be ready to begin operations and meet all state and local requirements. In addition to having a completed Minimum Standards review, facilities must have attended the mandatory Missouri Medical Marijuana Facilities Welcome Meeting and have no outstanding Business Change Request that would impact the facility's ability to become operational. Prior to the Commencement Inspection, facilities were required to provide standard operating procedures specific to their facility type and operations; become credentialed in Metrc, attend Metrc New Business training and become familiar with the system in order to demonstrate system proficiency during the inspection; have a fully built out facility according to their application for licensure; have a fully functioning security system; obtain Agent Identification (ID) cards for all applicable individuals/employees; and demonstrate compliance with 19 CSR 30-95 and Article XIV, as well as all applicable state and local laws and regulations. Once all documentation was received from the facility and verified by DHSS, a pre-inspection conference call was scheduled with the facility. A physical inspection was then scheduled and conducted as the final phase of the process. During the physical inspection of the facility, DHSS inspected the facility to verify compliance with all applicable rules and laws, specifically ensuring security and all physical aspects of the facility were ready for medical marijuana to be present in the facility.

When a facility is found to be in compliance, an Approval to Operate letter is provided and the licensee is allowed to have medical marijuana in the facility. When facilities are unable to meet the requirements to pass the Commencement Inspection, the request for a Commencement Inspection is set aside until they are able to successfully pass the inspection and become operational.

DHSS conducted the first two Commencement Inspections on June 1 and June 3 for cultivation facilities. On June 10, the first Approval to Operate letter was issued. The first two dispensary Commencement Inspections were conducted on August 18, and the first dispensary Approval to Operate letters were issued on August 28. DHSS conducted the first laboratory testing facility Commencement Inspection on September 25 and subsequently granted the facility Approval to Operate. This approval meant that medical marijuana sales could begin as soon as product had passed required testing. The first transportation facility Commencement Inspection was conducted on October 14, and the facility was issued an Approval to Operate on October 23. The first manufacturing facility Commencement Inspection took place on November 23, and the facility was issued an Approval to Operate on December 4. The manufacturing facility approval to operate was a major milestone for the industry in that at least one of each facility type was operational in Missouri and a full range of products could then be offered to patients. At the end of the program year, DHSS had received 67 Commencement Inspection requests (35 of which were in progress) and 32 were complete and approved to operate.

Figure 22

Data as of Dec. 4, 2020

Note 1: The total number of active licensed/certified facilities requiring a Commencement Inspection is 372.

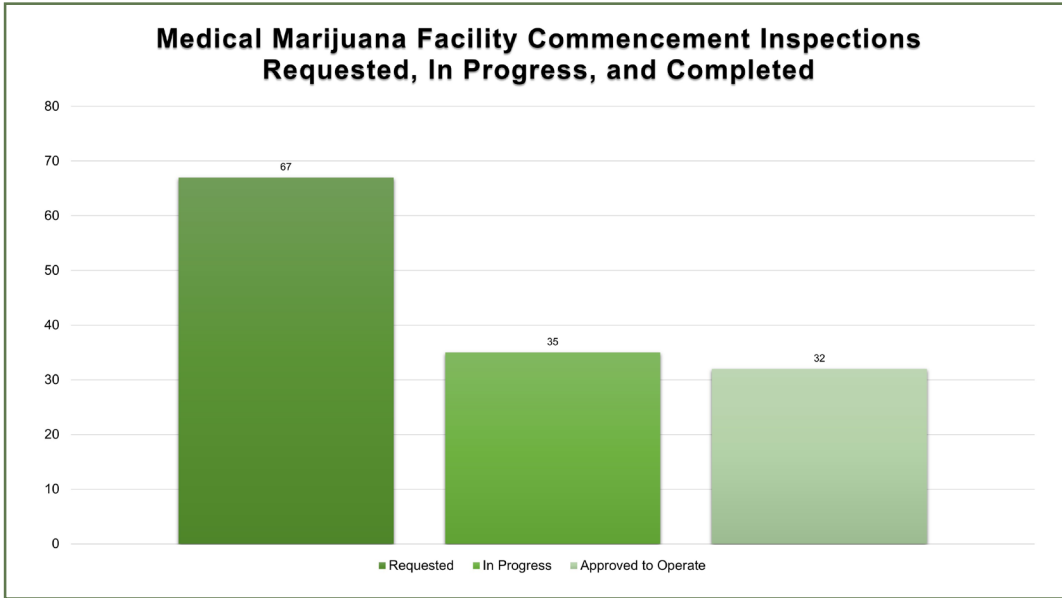
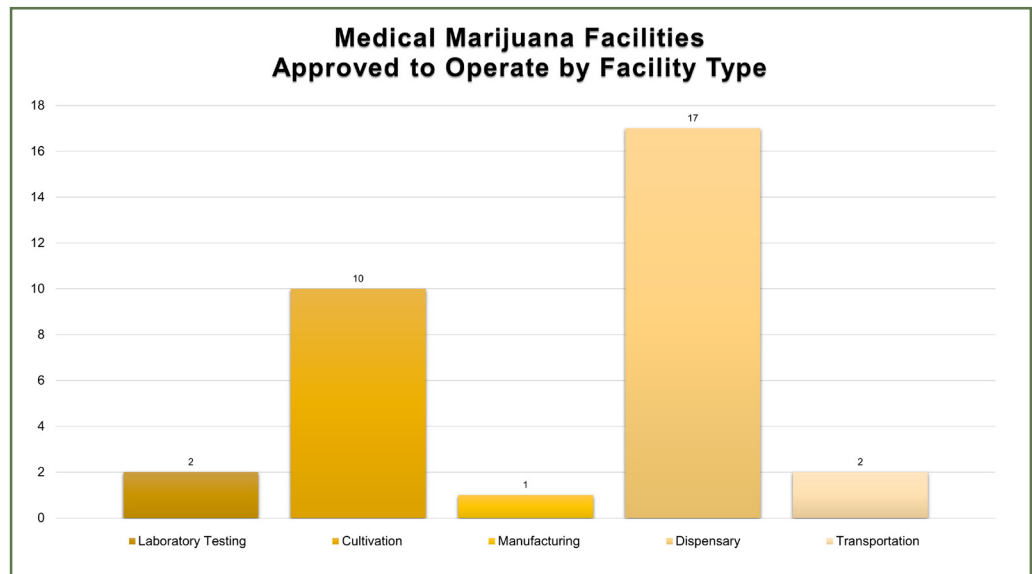


Figure 23

Data as of Dec. 4, 2020

Note: Each facility had to request a Commencement Inspection from DHSS when it had completed the Minimum Standards Review and was ready to begin operating. Once a facility completed the Commencement Inspection, it received approval to operate and began working with medical marijuana.



Over the course of the program year, a number of licenses were deactivated. Deactivation of a license can be due to surrender, revocation, or in cases where DHSS determines a facility was issued more than one license for duplicate infused-product manufacturing applications, licenses were merged and a refund was issued for the duplicate license. Below are the numbers of licenses deactivated for each reason.

Figure 24: Facility Deactivations

License Type	Surrender	Revocation	Merge	New Awards
Cultivation Facility	0	0	0	0
Dispensary Facility	3	1	0	3
Infused Product Manufacturing Facility	1	0	10	11
Laboratory Testing Facility	0	0	0	1
Seed to Sale	0	0	0	16
Transportation Facility	4	4	0	9
Total	8	5	10	40

For cultivation, infused-product manufacturing, dispensary, and laboratory testing facilities, deactivated licenses have been replaced with new licensees.

DHSS continued to award transportation and seed to sale certifications throughout the year. At the end of the program year, there were a total of 30 transportation certifications issued, seven surrendered, 22 active and one pending payment, and 17 certified seed to sale providers.

DHSS conducted a new survey of licensed facilities in August to assess available and projected supply of medical marijuana. Cultivation facilities were asked to estimate their planned production for 2021 and 2022. DHSS utilized these estimates to calculate the anticipated square foot (sq. ft.) of canopy space planned for use, the amount - in pounds - expected to be produced from this space, and average pounds produced per sq. ft. expected in the calendar year 2022. While some cultivation facilities indicated partial production capacity in 2021 and 2022, more than 50 percent of those who completed the survey anticipate using the entire 30,000 allowable sq. ft. of canopy space for their indoor grow facility.

Of that 50 percent, the estimated pounds produced per sq. ft. of canopy space ranged from 5,600 to 36,000 pounds for an average of 14,850 pounds for calendar year 2022. Based on these responses, the average pounds produced per facility is estimated to be .495 pounds per sq. ft. of canopy space. This estimate aligns with data in the 2019 *Missouri's Medical Marijuana Market: An Economic Analysis of Consumers, Producers, and Sellers*, which noted that the average indoor cultivation facility could annually produce approximately .5 pounds per sq. ft. of canopy space. Based on survey responses, the estimated production is between 262,217 – 268,217 pounds of medical marijuana for 2021 and between 396,548 – 402,548 pounds in 2022. Assuming all patients purchased the maximum amount allowed under Article XIV, this is enough production to serve a minimum of 87,406 patients in 2021 and 132,183 patients in 2022. An extensive review of publicly available medical marijuana program reports from 20 other states indicated that, on average, patients purchased significantly less than their maximum allotment. If Missouri follows this trend, there will be more than sufficient production to meet demand during implementation with facilities producing at partial capacity. At full capacity, there should be sufficient production to meet demand for Missouri's patients through at least 2026. The survey also assessed operational readiness, which aided DHSS in planning and preparing for Commencement Inspections and the submission of operational deadline variance requests.

DHSS began receiving requests for variance from the one-year operational deadline outlined in 19 CSR 30-95.040(1)(F)4 at the end of September. Due to the anticipated number of variance requests and in an effort to streamline the process, DHSS released the Questionnaire for Operational Variance in early November. Facilities requesting an operational deadline variance were required to submit the questionnaire along with the standard DHSS Variance Request Form at least seven days prior to their operational deadline. Using the questionnaire, licensees provided DHSS with the necessary information to determine whether the variance would be approved or denied. Licensees must show good cause for a variance to be approved. At the end of the program year, DHSS had received 103 operational deadline variance requests, of which 32 were processed and approved, and 71 were in the process of being reviewed.

Suspend, Fine, Restrict or Revoke Licenses and Certifications

DHSS is granted the authority to suspend, restrict, and revoke a license, as necessary, and impose administrative penalties in certain circumstances. Rules regarding violations and penalties are posted with all other regulations on the DHSS website.

Patient and Caregiver Enforcement

Between March and June 2020, there were two investigations into the issuance of fraudulent physician certification forms. During the investigations, it was determined that patient cards had been issued to applicants who submitted physician certification forms with unauthorized physician signatures. There were approximately 1,000 impacted patients, and all were contacted and given the opportunity to submit another physician certification in order to retain their patient card. Those who chose not to submit a new certification were refunded a pro-rated amount of their license fee, and their license was deactivated.

Currently, there are over 600 participating physicians certifying patients for the medical use of marijuana. As part of the original MMRP registry's design, DHSS is integrating an electronic Physician Certification Form process in the application registry portal. This integration will provide a secure method for protecting physician and patient information, and will reduce the potential of fraud related to submission of unauthorized Physician Certification Forms. Once the integration is completed in PY21, DHSS will no longer accept Physician Certification Forms that are uploaded by the patient as part of their application submission. Instead, certifying physicians will submit the electronic form via their approved accounts.

DHSS receives complaints from law enforcement and the public when individuals are suspected of violating Article XIV or 19 CSR-30-95. Each report or complaint is investigated and may result in the revocation of a patient, caregiver, or patient/caregiver cultivator license.

Facility Enforcement

The statewide track and trace system is an important regulatory tool for monitoring patient purchase limits and for preventing diversion of regulated product into the black market. All licensed facilities are required to track in this system all medical marijuana from seed or immature plant stage until the product is either destroyed or sold to a patient or caregiver.

Investigations related to tracking product or any other regulated activities can be initiated several ways. DHSS may receive a complaint about a licensed facility, or DHSS staff may discover an issue during an inspection or review. In either case, DHSS will determine if an investigation is warranted to substantiate the allegations or potential compliance issue. In the event an investigation is warranted, DHSS will provide the facility with a copy of the complaint and an opportunity to respond at the time of investigation.

If DHSS determines, during an inspection or investigation, that a facility is not in compliance with Article XIV or applicable rules and regulations, an Initial Notice of Violation will be issued to the facility explaining how the facility has violated the rules and what remedial or corrective actions the facility is expected to take to correct the violation(s). Once a facility has been notified of the violation(s), the facility is required to correct the violations within 15 days. DHSS will then conduct a follow-up inspection within 15 to 30 days to confirm the facility has corrected the violation(s). The facility must notify DHSS if they believe additional time to correct the violation(s) is needed, which may be granted for good cause.

If a follow-up inspection reveals the violation(s) have not been corrected, a Final Notice of Violation will be issued to the facility explaining how the facility continues to violate the rules and regulations, describing what remedial or corrective actions the facility is expected to take, and notifying the facility that its license or certifications will be suspended if the specified remedial action is not taken and the violation(s) corrected within 30 days. If the facility fails to correct the violation(s) within 30 days after a Final Notice of Violation, and no extension of this deadline was granted, the facility's license or certification will be suspended, the facility will be required to cease operations, and the facility must sign a corrective action plan designed to bring the facility into compliance. If, at any time, DHSS determines a facility presents an immediate and serious threat to the health and safety of the public or the facility's employees, the facility may be ordered to immediately suspend all or a part of its operations until the threat has been eliminated.

Appeal Process for License Denials and Revocations

Administrative Hearings

DHSS focuses a majority of its efforts on ensuring that patients, caregivers, and facilities know and understand what is required for an application to be approved and what is required to retain a license that is granted. 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.

Per Article XIV, a denial of license or identification card may be appealed to the State of Missouri Administrative Hearings Commission (AHC). The AHC acts as a neutral and independent tribunal to impartially review agency decisions. The right to an administrative hearing is contingent on the individual or business filing a petition with the AHC within 30 days after DHSS' decision is sent to the individual or business.

During PY20, the AHC received 39 appeals from the denial of a patient or caregiver card. There were no AHC order for DHSS to issue a patient or caregiver identification card. From December 2019 to February 2020, the AHC received 853 appeals from denied facility applicants. At the end of PY20, 753 facility appeals remain active. The decline in cases is a result of cases being dismissed or otherwise resolved in favor of DHSS.

Cases Filed with the Courts

In addition to appeals of denials before the AHC, ten court cases were active during PY20 challenging various aspects of the MMRP or actions taken by DHSS. Eight of those cases were dismissed or resolved in favor of DHSS based on written and oral argument.

In *Sarcoxie Nursery Cultivation Center, LLC, et al., v Randall Williams, et al.*, Case No. 19AC-CC00556, the Petitioner challenged DHSS' decision to limit the initial medical marijuana licenses to the minimum number established by Article XIV and its rules for a score increase for applicants located in an economically distressed area. The trial court found in favor of DHSS on all counts, holding DHSS' rules were valid and constitutional. The court specifically found DHSS' decision to limit facility licenses was made after "thoughtful deliberation of both the constitutionality and the practical effect" of that decision.

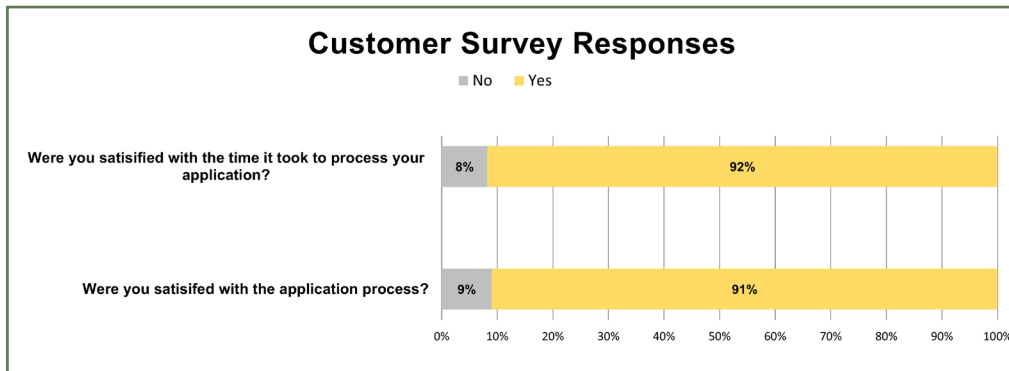
Stakeholder Engagements

DHSS utilizes several modes of communication in its efforts to provide education and transparency to the public, including: subscriber email list for patient services, Patient Services Newsletter, printed educational materials, press releases, community presentations, a robust website, and social media platforms.

Customer Satisfaction

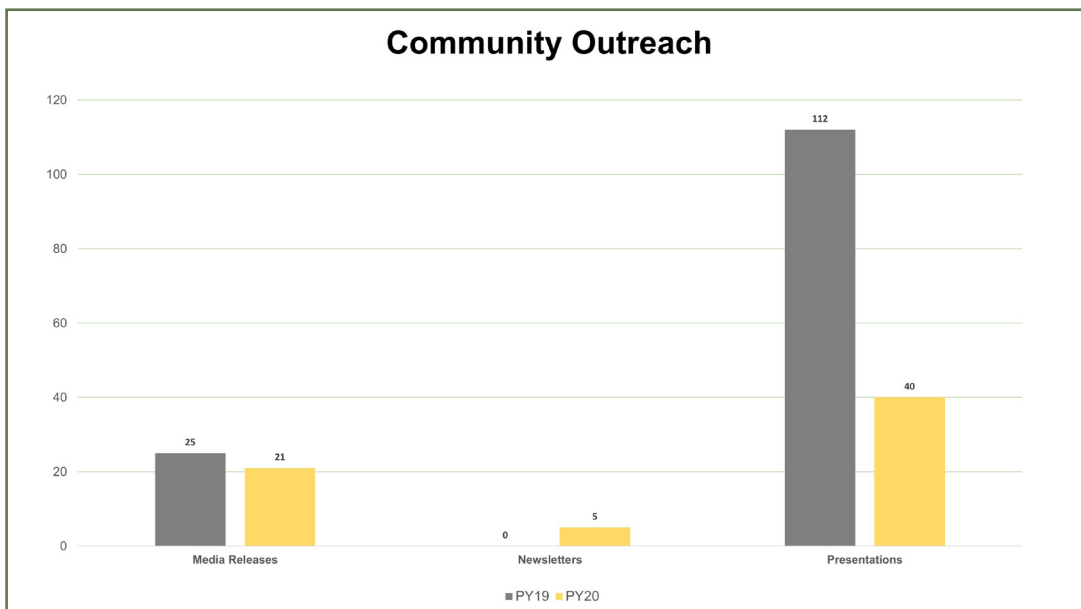
Public feedback is a valuable resource in maintaining a successful program. DHSS launched two surveys in 2020 on the Feedback webpage to allow the public to rank their satisfaction and provide their comments to DHSS' Webpage Survey and Customer Satisfaction Survey. A third survey assessing satisfaction with the application process is sent to each applicant, including facilities, as part of their application receipt confirmation email. All applicants are given opportunities to provide DHSS with feedback regarding their application experience. The majority of respondents are satisfied with the application process and the time it takes to process applications.

Figure 25



Communication and Education

Figure 26



A Patient Services email subscription was posted to the website in early spring 2020, and the first volume of the Patient Services Newsletter was issued to subscribers on April 1, 2020. At the close of PY20, there were 750 subscribers.

DHSS makes available some of its educational materials in printed form. These printed educational materials can be ordered, for free, from DHSS' warehouse. Some educational materials are only available in electronic format for public download from the website. Below is a list of printed materials available from the warehouse:

- Medical Marijuana Equivalency Card
- Patient Information Booklet
- Physician Information Brochure

DHSS received and responded to over 8,000 facility-related inquiries through its central email account apart from its regular communication with facilities. DHSS communicates with facilities on a regular basis through individualized email correspondence, industry-wide Guidance Letters, publicly available responses to frequently asked questions, and detailed Commencement Inspection information and meetings.

Website

The website offers current, concise content and easy to navigate links making it an ideal avenue for channeling communication and outreach. Unique page views are a metric that aggregates page views during a user's session and gives credit only once to each page viewed.

Figure 27: Number of Website Visits

January 2020 - November 2020	
Website	Unique Page Views
Home Page	114,515
Frequently Asked Questions	15,536
How to Apply	185,128
Rules	33,926

The following facility licensing and compliance information was publicly available on the website:

- Facility application scores and ranks along with individual score sheets.
- Facility guidance letters that were emailed to facilities.
- Weekly updates to charts and graphs showing the progress of DHSS, facilities, and the industry in implementing Article XIV
- Fillable complaint forms with submission instructions for complaints regarding patients or facilities.
- Fillable variance request forms with instructions for submission.
- Commencement Inspection forms and guidance documents.
- Listings of licensed medical marijuana facilities with their facility location and contact information.

Collaboration

Implementation of Article XIV impacts multiple state and local agencies, and collaborating with these agencies continues to be a priority. In PY20, DHSS led two formal workgroups focused on medical marijuana implementation, one of which includes representatives of numerous Missouri state agencies, and the other includes representatives of Missouri law enforcement entities.

DHSS also continues to connect with interstate workgroups, such as the Cannabis Regulators Roundtable, which brings together cannabis regulatory agencies with the intention of learning from other states' experiences and assisting each other in crafting solutions to shared concerns.

Conclusion

DHSS efficiently discharged its responsibilities under Article XIV and associated rules. The implementation time for Missouri's medical marijuana program, from law passage to first sale, was less than 24 months, which was well under the national average of 29 months for states implementing medical marijuana programs since 2005.

The MMRP's primary focus for PY20 was issuance of facility licenses, verification that each licensee's application was truthful and transparent regarding minimum standards for licensure, and shepherding licensees toward and through the commencement inspection process. As more facilities continue to become operational, DHSS is entering the final stages of implementation in activating its compliance and enforcement operations.

In the upcoming program year, DHSS will continue to monitor facilities' progress and how well facilities are meeting the needs of patients. This will require strong collaboration with Missouri's licensed facilities and patients, balanced by fair and impartial application of the law. DHSS will pursue public engagement and transparency, which has always been a key component of its success, and further develop consistent regulation, enforcement, and education in order to ensure DHSS is successful in providing safe and secure access to medical marijuana for qualifying Missouri patients.

Appendix A: Implementation Dates

The list below provides specific dates to key implementation activities.

- **12/19/19:** Issued licenses to 10 laboratory testing facilities.
- **12/23/19:** Issued certifications to 21 transportation facilities.
- **12/26/19:** Issued licenses to 60 cultivation facilities.
- **1/9/20:** Held public forum on medical marijuana vaping issues.
- **1/10/20:** Issued licenses to 86 infused-product manufacturing facilities.
- **1/23/20:** Issued licenses to 192 dispensary facilities.
- **1/31/20 – 02/26/20:** Issued certifications to seed to sale vendors.
- **January 2020-February 2020:** Conducted mandatory readiness/information gathering survey for all facility types.
- **2/5/20:** Conducted mandatory survey of laboratory testing facilities.
- **3/3/20:** Posted draft rules revisions to the website for public comments.
- **3/4/20:** Held Facilities Welcome Meeting for cultivation, manufacturing, laboratory testing and transportation facilities.
- **3/5/20:** Held Facilities Welcome Meeting for dispensary facilities and seed to sale vendors.
- **4/1/20:** Launched Missouri Medical Marijuana Program Patient Services Weekly Newsletter.
- **4/9/20:** Held a call with representatives from Missouri law enforcement associations, Department of Public Safety and Department of Corrections to provide updates on Missouri Medical Marijuana Regulatory Program implementation and rules.
- **5/1/20:** Statewide Track and Trace system went live.
- **5/12/20:** Published adjusted fee schedules for facilities and patients.
- **6/1/20:** Conducted first Commencement Inspection.
- **6/5/20:** Released the first Annual Report to the Governor for PY19.
- **6/5/20:** Posted two new graphs to the website regarding facility compliance measures tracking.
- **6/8/20:** Reactivated the toll-free Patient Services Customer call line after its suspension during the State's response to the covid-19 pandemic.
- **6/10/20 – 6/11/20:** Issued first two Approval to Operate notices to cultivation facilities.
- **7/14/20:** Posted 16 User Guide Video Tutorials to website to assist patients and caregivers with creating and managing their application in the MMRP.
- **7/16/20:** Redesigned facility webpages to include new Facility Resources page and a redesigned landing page with user-friendly topic buttons.
- **8/28/20:** Issued the first two Approval to Operate notices to dispensary facilities.
- **9/9/20:** Published Patient/Caregiver Cultivator Complaint Form to website.
- **9/11/20:** Transferred \$2.1 million to the Missouri Veterans Commission.
- **9/25/20:** Issued the first Approval to Operate notice a laboratory testing facility.
- **10/16/20:** First medical marijuana sales to patients in Missouri.
- **10/23/20:** Issued the first Approval to Operate notice to a transportation facility.
- **10/30/20:** Testified in *Sarcoxe Nursery Cultivation Center, LLC, et al., v Randall Williams, et al.*, Case No. 19AC-CC00556 (See Appendix C for ruling information).
- **12/4/20:** Issued the first Approval to Operate notice to a manufacturing facility.
- **12/5/20:** Issued a total of 33 licensed facility Approval to Operate by the end of PY20.

Appendix B: Active Qualifying Patients by Condition

Active Qualifying Patient Count by Condition for Program Year 2020	
Condition	Number of Active Patients by Condition
Any Terminal Illness Category	
Cancer	2,204
Other Terminal Illness (not defined)	65
Cachexia	13
Sickle Cell Anemia	11
Amyotrophic Lateral Sclerosis	8
Huntington's Disease	3
Chronic Medical Conditions Category	
Other Chronic Medical Conditions (not defined)	17,492
Neuropathies	500
HIV	440
Crohn's Disease	374
Inflammatory Bowel Disease	278
Hepatitis C	188
Autism	58
Wasting Syndrome	6
Other Conditions Category	
Other Conditions (not defined)	9,522
Epilepsy	844
Glaucoma	631
Alzheimer's Disease	11
Individually Listed Conditions	
Physical/Psychological Dependence	20,988
Psychiatric Disorders	11,914
Migraines	3,843

Appendix C: Sarcoxie Nursery Cultivation Center, LLC, et al., v Randall Williams, et al., Case No. 19AC-CC00556

By the time of the Annual Report's printing, the court issued its ruling in Case No.19AC-CC00556 in favor of DHSS. The following are brief excerpts from the court ruling:

- DHSS regulations regarding limitations on the number of licenses issued in the state and economic impact scoring are valid and constitutional and do not conflict with state law. The plain language of Article XIV contemplated facility license limitations, and DHSS was authorized to implement such limits.
- Economic impact scoring adjustments are not special laws and the state has a legitimate governmental interest in improving the economic conditions of communities within the state. It does not impair patient access to allow economic impact scoring adjustments in the scoring and ranking process for facility applications.
- License limits bear a rational relationship to legitimate government interests, including:
 - The effectiveness of governmental oversight and regulation decreases as the number of facility licenses increases as licensees would be progressively less qualified;
 - The government must incur additional regulation costs to ensure destruction of excess marijuana when facilities are incentivized by oversupply to sell excess marijuana into the black market; and
 - Unlimited licenses result in putting patients at risk as government has finite resource to regulate.
- If a rule bears a rational relationship to a legitimate state interest, it is neither arbitrary nor capricious. DHSS demonstrated that license limits were put in place after thoughtful deliberation of their constitutionality and practical effect.



Missouri Department of Health and Senior Services

Division of Regulation and Licensure

Section for Medical Marijuana Regulation

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[MedicalMarijuana.Mo.Gov](https://www.MedicalMarijuana.Mo.Gov)

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An EO/AA employer: Services provided on a nondiscriminatory basis.

Individuals who are deaf, hard-of-hearing, or have a speech disability can dial 711 or 1-800-735-2966.