

# MISSOURI MEDICAL MARIJUANA

## FACILITIES WELCOME MEETING



## WELCOME MISSOURI MEDICAL MARIJUANA FACILITIES!

### **ANDREA BALKENBUSH** FACILITIES LICENSE & COMPLIANCE DIRECTOR



## Logistics

- Location of restrooms
- Coffee and water station
- Question cards
- Networking opportunities
- Lunch hour
- Name badges





# WELCOME

### **DR. RANDALL WILLIAMS** DEPT. OF HEALTH & SENIOR SERVICES DIRECTOR



## **DHSS Mission and Vision**

- Mission: to be the leader in promoting, protecting and partnering for health
- Vision: Healthy Missourians for life





# WELCOME

### LYNDALL FRAKER

DIRECTOR, SECTION FOR MEDICAL MARIJUANA REGULATION



## **SMMR** Mission and Vision

### 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

### Vision

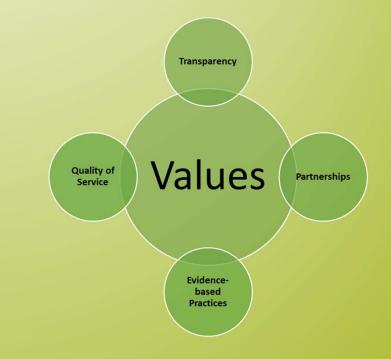
 A program that provides safe and secure access to medical marijuana for qualifying Missouri patients through consistent regulation, enforcement and education





### Vision & Values

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





## **SMMR Strategic Priorities**

#### Strategic Priority #1

Make medical marijuana accessible for qualifying patients

#### Strategic Priority #2

Uphold safety and quality standards for medical marijuana

#### Strategic Priority #3

Regulate the medical marijuana industry to comply with Missouri law and keep communities safe

Employ modern tools and best practices to streamline and integrate processes



### Principles

- Flexible and Scalable
  - Create a well regulated and enforced patient-focused program that safely and effectively provides access to Medical Marijuana for qualified residents of Missouri in order to meet their medical needs
- Transparent and Accountable
  - <u>Create a level playing field</u> by enforcing all regulatory requirements in a firm, transparent, and consistent manner
- Customer-Oriented
  - Learn from other states that have gone through this process



### **History & Key Dates**

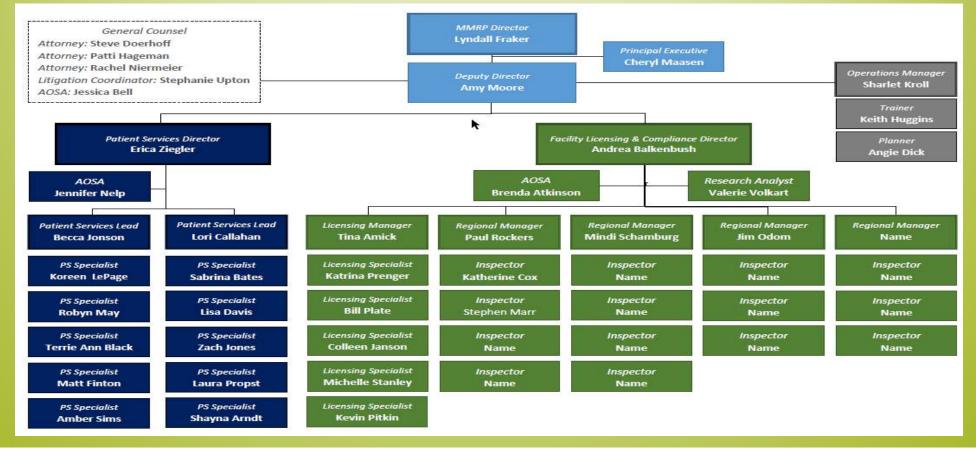


**Mar 4 Facilities** 

We are here! :



### **SMMR** Organizational Structure



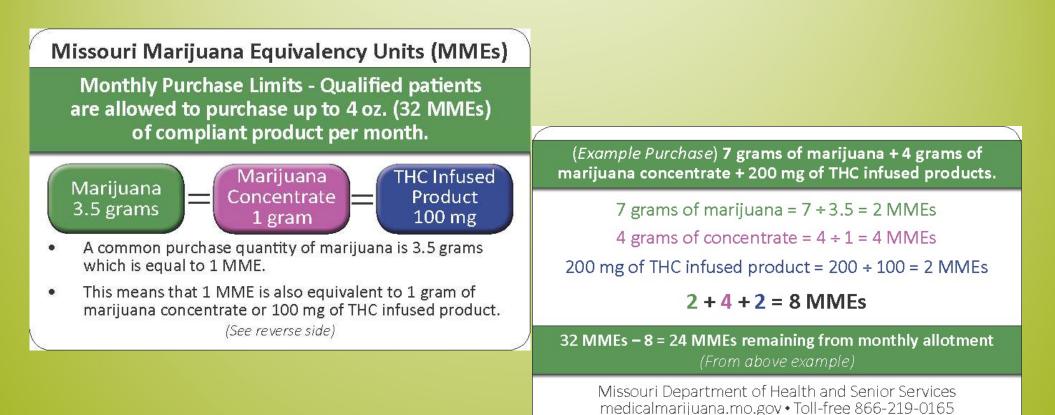


## **Program Statistics**

- Over 35,000 Registered Patients
- Nearly 1,000 Registered Caregivers
- Over 11,200 Patient/caregiver cultivators
- Over 2,200 Facility Applications Received
- Over 370 Licenses Awarded
  - 10 Licensed Laboratory Testing Facilities
  - 60 Licensed Cultivation Facilities
  - 86 Licensed Infused Product Manufacturing Facilities
  - 192 Licensed Dispensary Facilities
  - 22 Licensed Transportation Facilities
  - 7 Licensed Seed to Sale Vendors







#203 09/2019



## Questions





## COMMUNICATION, RESOURCES & COLLABORATION

### **ANDREA BALKENBUSH** FACILITY LICENSE AND COMPLIANCE DIRECTOR



## **Meeting Purpose**

- Introduce facility attendees to SMMR license and compliance
- Review facility expectations, methods of communication and available resources
- Provide information for current and upcoming regulatory processes
- Answer facilities questions
- Establish good working relationships

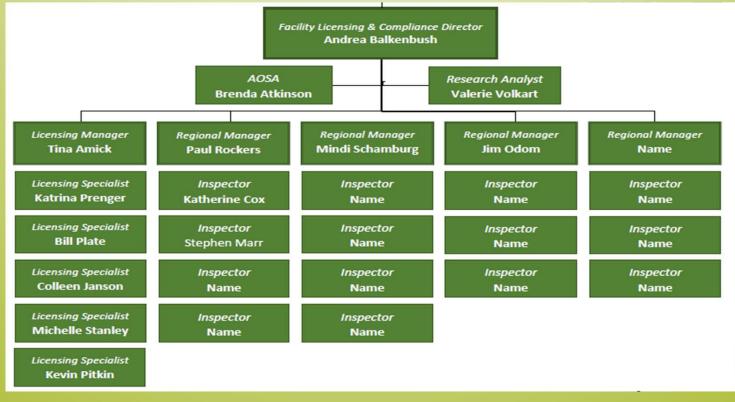


## **Meeting Objectives**

- Review variance, complaint and rules update processes
- Review facility licensing timeline, minimum qualifications and business update changes
- Learn about the commencement inspection process and what to expect
- Review the Agent ID cards, requirements and application process
- Learn about the state track and trace system and Seed-to-Sale integrators
- Provide an opportunity for licensees to network with each other, SMMR staff and other state agency staff
- Opportunity for questions



### Facility License and Compliance Organizational Structure





## **Section for Medical Marijuana**

- Director
  - Lyndall Fraker
- Deputy Director and Counsel
  - Amy Moore
- General Counsel
  - Patti Hageman
  - Stephen Doerhoff
  - Rachel Niemeier

- Patient Services Director
  - Erica Ziegler





### Facility License and Compliance Team

- Administration
  - Director
    - Andrea Balkenbush
  - Administrative Assistant
    - Brenda Atkinson
  - Research Analyst
    - Valerie Volkart

- License
  - Licensing Manager
    - Tina Amick
  - Licensing Specialists
    - Colleen Janson
    - Kevin Pitkin
    - Bill Plate
    - Katrina Prenger
    - Michelle Stanley

- Compliance
  - Regional Managers
    - Jim Odom
    - Paul Rockers
    - Mindi Schamburg
  - Inspectors
    - Katherine Cox
    - Stephen Marr
    - 6 Compliance Officers Mid-March Start



### State Track and Trace System Metrc

#### **David Eagleson**

Metrc, Program Management Director

#### **Riley Sisk**

Metrc, Government Program Manager



## Collaboration

- To ensure the success of Missouri's Medical Marijuana Program and access to care for qualified patients, SMMR will regularly collaborate with:
  - SMMR staff
  - Local communities
  - Local and state law enforcement
  - City officials
  - Other medical marijuana facilities
    - Share Best practices
    - Share Resources

We encourage you to collaborate





## State Agency Staff

Department of Agriculture

Department of Revenue

 Department of Labor and Industrial Relations

Missouri State Highway Patrol

Department of Natural Resources



## **Communication & Compliance First**

#### Open Communication First

- It's a two way street
- Keep us informed
- Outline Expectations

#### Compliance First

- We want you to be successful
- Help you to be in Compliance
- It's a two way street

#### Duty to Enforcement

- Ensure fairness in the industry
- Uphold Article XIV and 19 CSR 30-95
- Ensure patient and community safety





## Communications

- <u>All</u> communications will be sent by <u>email</u> to the facility's Primary Contact
- No communication will be sent through regular mail
- Methods of communication
  - Email
  - In-person
  - Phone
  - Listserv
  - Medical Marijuana Registry Portal
  - Surveys





## **Compliance First**

- Collective goal for all Missouri's Medical Marijuana facilities to achieve compliance.
- All take necessary steps to be and stay in compliance with Article XIV and 19 CSR 30-95
- SMMR will do what we can to help facilities achieve compliance by:
  - Open lines of communication
  - Answering questions
  - Providing guidance
  - Compliance Visits



## **Facility Compliance**

- Facilities must comply with Article XIV and 19 CSR 30-95
  - Licensee's responsibility to know the rules associated with each facility type
- Respond to requests for information
- Provide requested documentation
- Obtain Department approval prior to taking actions where needed
- Inform the Facility License and Compliance Section of any changes or deviations from what was submitted in your application

## Better to ask the question or receive guidance, then to ask for forgiveness later



## **Important Notes for Licensees**

- The issuance of a license or certification does not authorize the facility to begin operations.
- A facility will be granted final approval to operate upon passing a commencement inspection.
  - Facilities have up to 1 year to pass commencement.
- The facility will, at all times, comply with Article XIV and all other applicable laws and regulations.
- License Changes



## **Facility Compliance**

- All lots of medical marijuana produced by a cultivation or manufacturing facility <u>must</u> be tested by a licensed laboratory testing facility
- Testing will only be performed on the final medical marijuana product equivalent to what will be dispensed to the patient
- All cultivation and manufacturing facilities <u>must</u> make arrangements to have their products tested by one of the Missouri laboratory testing facilities
  - A listing of approved and denied laboratory testing facilities can be found at <u>https://health.mo.gov/safety/medical-marijuana/</u>
- <u>Medical marijuana facilities may not transfer medical marijuana from their</u> <u>facility until it has passed all required testing.</u>



### Laboratory Testing Facility Readiness

- Laboratory testing facilities Commencement Inspection readiness
  - First Quarter (January March) = 1
  - Second Quarter (April June) = 3
  - Third Quarter (July September) = 4
  - Fourth Quarter (October December) = 2



### Resources

#### **Facility Licensing and Compliance**

DHSS Home » Licensing & Regulations » Medical Marijuana » facilities

#### https://medicalmarijuana.mo.gov

MMfacilities@health.mo.gov

Facility Information	^
Facility Licensing and Compliance	
Licensed Facilities	
Application Score and Rank	
MMRP License and Compliance Guidance Letter	
Facility License and Compliance Section Web Comment Form	
Facility License and Compliance Variance Request Form	
Facility Application Fingerprint Instructions	
Facility Agent ID	
Fee Schedule	
Frequently Asked Questions	
How to Apply	
Facility - Rejected Applications	
Seed to Sale	



## **Facility Resources**

- Medical Marijuana Facility Licensee Resources webpage
  - Coming soon!
- Guidance Documents
- Facility License & Compliance Comment Form
- Variance Request Form
- Complaint Form
- Agent Id
- E-mail Address for Facility Licenses
  - <u>MMfacilities@health.mo.gov</u>



## **Program Resources**

#### **Medical Marijuana Regulation**

DHSS Home » Licensing & Regulations » Medical Marijuana

- Article XIV and
- Medical Marijuana Rules: 19 CSR 30-95
- Frequently Asked Questions for Facilities
- 24/7 Missouri Business



### https://medicalmarijuana.mo.gov



## **On-Going Application**

- Transportation certification
  - The Department will issue certifications for all eligible Transportation entities.
  - Licensed facilities do not need additional Transportation Certifications
- Seed to Sale Certification
  - The Department will issue certifications for all eligible Seed to Sale entities.
  - Must sign and API agreement and pass certification with State's Track and Trace System



## **Facility Fees**

#### Fees and Payments

- Annual Fees
  - due 30 days after a facility is licensed.
- Will I receive a written notice?
  - No, it is the licensee's responsibility to submit the appropriate payment by the due date
- How can I pay my annual fee?
  - Fee payments must be made through the Medical Marijuana Registry system.
  - If for some reason, this is not possible, e-mail <u>mmlicenses@health.mo.gov</u> for assistance.



License/Certification Type	New Application Fee	Annual Fee	Renewal Fee	New Application Fees
<b>Cultivation Facility</b>	\$10,000	\$25,000	\$5,000	\$5,000
<b>Dispensary Facility</b>	\$6,000	\$10,000	\$3,000	\$3,000
Facility Agent	\$75		\$75	\$75
Laboratory Testing Facility	\$5,000	\$5,000	\$5,000	\$5,000
Manufacturing Facility	\$6,000	\$10,000	\$3,000	\$3,000
Seed to Sale	\$5,000	\$5,000		\$5,000
Transporter	\$5,000	\$5,000	\$5,000	\$5,000



## Questions





# MISSOURI RULES AND REGULATIONS

## **AMY MOORE** DEPUTY DIRECTOR AND COUNSEL



## Objectives

- Variance Request Process
- Complaints
- Changes to Rules
- Rule Violations
- Facility Change Requests



## Variance Request Versus Facility Change Request

Change Requests that require prior approval from SMMR

• Five categories – 19 CSR 30-95.040(4)(C)



## Variance Request Versus Facility Change Request

Variance Request

- Entity is asking the department to waive or vary from a rule
  - 19 CSR 30-95.025(2)



## Variance Process

Entity is asking the department to

waive or vary from a rule 19 CSR 30-95.025(2)

- Per 19 CSR 30-95.025 (2), requests for variance from the requirements of any provision of rule shall be made in writing by the facility's primary contact person
- A variance request is separate from a business update change request



## Variance Process

- Variance requests must include:
  - A list of each requirement for which a variance is requested,
  - Citation to specific rule in which the requirement can be found; and
  - An explanation for why the requirement cannot be met or why meeting the requirement would impose an undue burden on the licensee.

### Sufficient good cause must be included



## **On-Line Fillable Variance Form**

#### Per 19 CSR 30-95.025 (2), requests for variance from the requirements of any provision of 19 CSR 30-95 shall be made in writing by the primary contact person on record for a Facility License or Certification, or for a facility application.

Any variance request received will be reviewed based on the information provided and the proposed good cause.

We cannot guarantee a variance will be granted. The requester should continue to meet department established deadlines while a variance request is pending. The department does not have a specific timeframe established for approving or denying a variance request. A variance request made 7 days in advance of deadlines is preferred to allow the program an opportunity to sufficiently review. A variance request shall be issued by the department in writing and shall include the specific reasons for an approval or a denial.

If a variance is not granted, the facility or applicant may be in violation of the rules per 19 CSR 30-95.040 (5)(C). A facility's violation of rules many result in revocation of its license or certification.

Variance requests shall include:

- A list of each requirement for which a variance is requested, with citation to the specific rule in which the requirement car be found; and
- An explanation for why the requirement cannot be met or why meeting the requirement would impose an undue burden
- on the applicant or facility.
   The Variance must also include good cause.

Multiple variance requests should be submitted separately

Requests for variance from the requirements of any provision of 19 CSR 30-95 shall be made by completing this form in its entirety.

Submit this form to: mmlicenses@health.mo.gov Attenti	ion: Variance Request.
FACILITY INFORMATION	
FACILITY NAME[1]	FACILITY LICENSE ID[2] Limit dialog box to 9 characters
FACILITY PHONE #	APPLICATION ID [3] Limit dialog box to 9 characters
FACILITY STREET 1	STREET 2
FACILITY CITY	5T 22P AT E
PRIMARY CONTACT INFORMATION [4]	
PRIMARY CONTACT NAME	
PHONE #	EMAIL
STREET 1	STREET 2
CITY	ST ZIP AT E
CONTACT OF AGENT, IF APPLICABLE [5]	
AGENT NAME	

New fillable Variance Request From will be posted to the SMMR website soon

### Complete the form in its entirety

Email to <u>mmlicenses@health.mo.gov</u>



## **Complaint Process**

Per 19 CSR 30-95.025(3), all complaints against licensed or certificated medical marijuana facilities must be submitted using the Complaint Form



## **Complaint Process**

- The Complaint Form must include:
  - Facility Name and License ID (if known)
  - Complainant Contact information
  - Indication of whether the complaint is being submitted by a facility employee
  - Citation of Article XIV or 19 CSR 30-95 provisions being violated
  - Summary of complaint (400 words or less)
  - Indication of supporting documentation attachments



## **On-Line Fillable Complaint Form**

Per 19 CSR 30-95.025(3) Complaints, all complaints against licensed or certificated medical marijuana facilities must be submitted using this form. Complaints shall include the name and address of the facility against which the complaint is made and a clear description of what violation the complainant believes the facility has committed.

- (A) Upon complaint against a facility, the department will determine whether an inspection is warranted to investigate the allegations in the complaint.
- (B) If the department conducts an inspection, the facility will receive a copy of the complaint.
- (C) Employees of a facility who report potential violations by a facility to the department may not be subjected to retaliation of any kind, including termination, because of their report.

Multiple complaints should be submitted separately. Once complete, submit form and any attachments to: MMlicenses@health.mo.gov

	ACILITY LICENSE ID, if know [2] Limit dialog box to 9 characters
EMAIL	
FAXINU	IMBER
STR	EET 2
ST	ZIP
AT	
E	
	EMAIL FAX NU STR ST AT

Complaint Form will be posted to the SMMR website soon

## Email completed form and any attachments to

mmlicenses@health.mo.gov



## **Rules Update Process**

- Medical Marijuana rules posted to the Section's website at <u>https://health.mo.gov/safety/medical-marijuana/draft-rules.php</u>
- Draft revisions posted to the website for input
- Comments or suggestions on draft revisions should be submitted through the online Suggestions Form or to <u>MedicalMarijuanaInfo@health.mo.gov</u>.
- After making any necessary changes based on public input, the final rules are submitted to the Secretary of State for publication in the *Missouri Register*
- Next Update



## **Violation of Rules**

### Violations, Compliance Verification Inspections, and Suspension

- If facility is not in compliance with the department's regulations
  - Initial Notice of Violation is sent
- Facility shall correct the violations within fifteen (15) days



## **Violation of Rules**

### Violations, Compliance Verification Inspections, and Suspension

- If follow-up inspection reveals the violations have not been corrected
  - Final Notice of Violation
- What remedial actions the department expects the facility to take
- Violations will have thirty (30) days to correct
- If no extension of this deadline has been granted by the department,

Facility's license or certification will be suspended



## **Facility Enforcement**

Violation	Penalty
A facility uses combustible gases or other dangerous materials to extract resins from marijuana without a manufacturing facility license	<ul> <li>⇒ Suspend License for up to one (1) year</li> <li>⇒ Fine of ten thousand dollars (\$10,000)</li> </ul>
A facility violates any provision in 19 CSR 30-95.010 or fails to comply with a corrective action plan	Suspend or Revoke License
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> <li>Suspend or Revoke License</li> <li>Fine of (\$5,000) for each category of improperly packaged product</li> <li>Improperly packaged medical marijuana will be recalled for repackaging or disposal, at the department's discretion</li> </ul>
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	⇔ Revoke License
A facility fails to comply with a department order to immediately suspend all or a part of its operations	⇔ Revoke License
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	⇔ Revoke License



### Department prior Approval Required – Business Update Change Request 19 CSR 30-95.040 (4) (C) 1- 5

- Ownership changes, ten percent or more
- Material deviation to proposed/current physical design, including location
- Combining licensed facilities (same or different ownership) to a single location
- Construction of a Warehouse
- Assign, sell, give, lease, sublicense, or otherwise transfer a license
- \$2,000 Fee Per Change Request



## Questions





## BREAK AND NETWORKING OPPORTUNITY

### VISIT WITH FACILITY LICENSE AND COMPLIANCE STAFF AND MISSOURI STATE AGENCIES



# FACILITY LICENSING AND CERTIFICATION

## **TINA AMICK** FACILITY LICENSE MANAGER

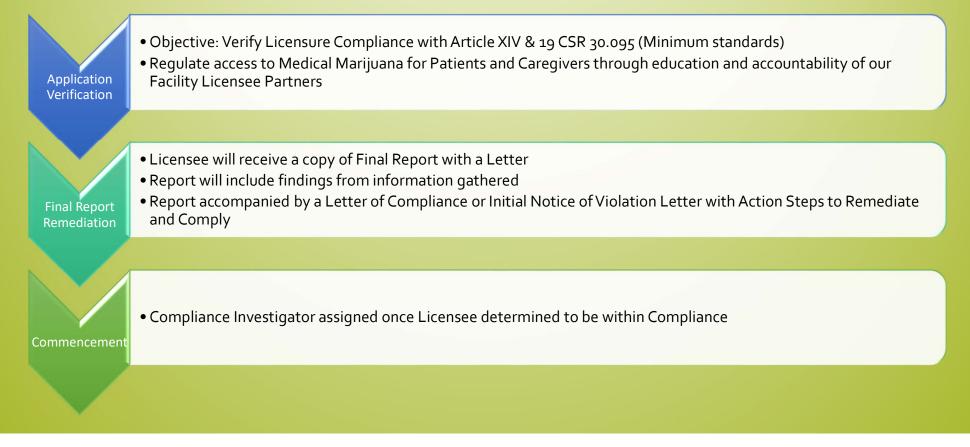


## **Facility License Compliance**

- Timeline of Events
- Application Verification Process
  - Objective
  - Schedule of Licensee Reviews
  - Document Request Letter
  - Registry System
  - Resources
  - Final Report
- Change Request Process
  - What is considered a change
  - When can I initiate a request?
  - How do I initiate a request ?
  - Cost Fee Schedule
- Future License Compliance Reviews
  - What can I expect?



## Path to Commencement Inspection





## Change is <u>inevitable</u>

- Application Verification Process
  - Does the Facility Licensee meet the conditions by which it applied and was Licensed?
  - Is the Licensee known to be in violation of rule
  - Document Request is not an official Change Request





Do you attest that the information provided in this application is true and correct? : YES

- What circumstance(s) perpetuated the change since application submission?
- Is the change necessitated by circumstances out of the control of the Licensee?
- Did the Licensee provide documentation to support the deviation from the original application?
- Did the Licensee receive a score adjustment (Zip Code, Location) that they may or may not have received as a result of the deviation/change?





## **Document Request Letter**

- Initiated by Assigned License Specialist to Primary Contact on file
- Priority of Reviews
  - Testing Labs
  - Entity Groups based on Readiness Response to Survey Results
- Multiple Licensees Under Review
- Turn around
  - Request will be seven calendar days
  - Expediting on your end helps keep things moving
  - Five business days for most entities to Final Report



## **Documents Requested**

- Required Documents
  - Personal Disclosure Form
  - Architectural Blueprints/Drawings (Mailed)
  - Operating Agreements
  - Application Questionnaire and Affidavit
- Examples of Other Documentation which may or may not be requested
  - Proof of Residency
  - Affidavits
  - Lease Agreements, Branding Agreements, Shareholder Agreements, Stock Purchase Agreements, Contractor Agreements, Profit Share Agreements, etc.
  - Maps in greater detail of Facility in proximity to all other buildings
  - Ordinances, Zoning Permits, City Attestation to Operate
  - Background Check Results





## Silence is not Compliance

- Requested documentation should support all information at the time of application
- If a change has occurred, at a minimum provide an explanation
- Provide documentation to support the change
- Failure to respond to any document request will be notated in the Department's Final Report





## How do I Submit Documents

- Use the Medical Marijuana Registry Portal (Complia) System
  - One submission in progress at a time
  - System limitations 24 uploads
  - Upload to the Business Updates
  - Mail Architectural Blueprints
- Resources Web Page
  - Coming soon!

When someone asks if they can fax me something.





## **Personal Disclosure Form**



Medical Marijuana Regulatory Program Personal Disclosure Form

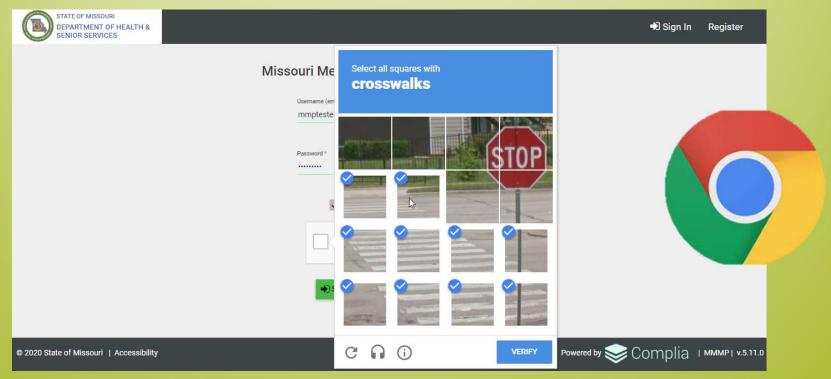
#### Instructions

- Please read all instructions carefully before completing this form.
- Definitions provided below.
- This form must be completed by every individual with any interest in, direct or indirect, or affiliation with, including through oral or written agreement, of the Licensed Entity by which this request was generated, when the individual would 1) incur or stand to incur economic gain/loss as a result of the interest in or affiliation with the Licensed Entity or 2) hold management or operating authority over the Licensed Entity as a result of the interest in or affiliation with that entity.
- It is not necessary for individuals employed by the Licensed Entity who receive <u>solely</u> earned income from Licensee Entity (Employment/Wages Income) to complete this form unless the individual has an interest in or affiliation with the Entity listed above. If in question, please contact your Licensed Specialist for clarification of who must complete this form.
- Do not leave blank spaces. If a field does not apply, indicate with N/A.
- All entries should be typed except signatures.
- · Signature and date in blue ink is required of the Individual for whom the Personal Disclosure is being completed.



## Medical Marijuana Registry Portal

https://mo-public.mycomplia.com/





## Medical Marijuana Registry Portal

https://mo-public.mycomplia.com/

				01	lelp 🌲 User Account 🗸
Licenses					٣
Status	Application ID	Title	License Type	License Number	Expiry Date 🛧 Actions
Approved	1098	MMPTestCompany2	New Business	TRA000003	<ul> <li>View License</li> </ul>
			Page:	1 👻 Rows per page:	🕹 Download License >
	Status	Status Application ID	Status Application ID Title	Status     Application ID     Title     License Type       Image: Approved     1098     MMPTestCompany2     New Business	Licenses         Status       Application ID       Title       License Type       License Number         Image: Colspan="3">Optication ID         Title       License Type       License Number         Image: Colspan="3">TRA000003



## Medical Marijuana Registry Portal

https://mo-public.mycomplia.com/

 Reminder: Only upload information to support application information by which you were licensed – no changes

Applications / Busi	ness License Update							
LICENSE INFORMATION	GENERAL	PERSONS OF INTEREST	LOCATION	PRIMARY CONTACT	QUESTIONS	DOCUMENTS	PAYMENT	REVI
			drop down. Please not the document requirer					- ALCON
License Number *			Please descri	be the nature of this u	pdate.			
TRA000003			*					
								0 / 50
	it an annual payment?				No			0 / 5(
Does this update ap other entity and/or	oplication assign, sell, lea		erwise transfer its license the ownership interests o	f the				0 / 50
Does this update ap other entity and/or facility?	oplication assign, sell, lea make changes to ten per	cent (10%) or more of	the ownership interests o	f the	No No			0 / 50
Does this update ap other entity and/or facility?	oplication assign, sell, lea make changes to ten per	cent (10%) or more of		f the				0/5
Does this update ap other entity and/or facility? Does this update ap of the facility?	oplication assign, sell, lea make changes to ten per	cent (10%) or more of rial deviation from the	the ownership interests o proposed or current phys	f the 🚯	No No			0/5



## Medical Marijuana Registry Portal

https://mo-public.mycomplia.com/

 Reminder: Only upload information to support application information by which you were licensed – no changes

DEPARTMENT OF HEALTH & SENIOR SERVICES						Help	🏝 User Acco	unt ~
	Applications / Bus	iness License Update						
Selected Account: MMPTestCompany	LICENSE INFORMATION	GENERAL INFORMATION	PERSONS OF INTEREST	LOCATION INFORMATION	PRIMARY CONTACT	QUESTIONS		NT REVIEW
+ CREATE NEW APPLICATION	IMPORT			ATION QUESTIONS BE	1 OW: Workshool	te nocoseary f	for answering Facil	ity
LICENSE DASHBOARD	Application	n Questions can be fo	und at https://healtl	n.mo.gov/safety/medic the Facility Application	al-marijuana/fa	qs-facility.php	. Fill out the applic	able
APPLICATIONS	Labeling eac	ch page of an attachm	ent with a business	in responses and on w name that must be re	dacted would cre	ate unnecess	ary strain on the s	ystem
O ACCOUNT V				thereby doubling the n as well as on the worl				an be
	C S Lie	cense Acceptance Letter				O UPLOAD	NEW	+'
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				Ð				



## **Final Report**

- License Specialist forward to Manager, Director
  - Legal review/final determination
  - Report outlines Findings, Compliance or Violation(s)
- Letter with Report Emailed to Primary Contact
- Compliance Letter
  - No Violations cited, Recommend Scheduling of Commencement
    Inspection
- Initial Notice of Violation Letter 19 CSR 30.095 (5) (C)
  - Findings and Violation(s) noted
  - Identified actions on Licensee's part to remediate
    - 15 days
    - Documentation demonstrating compliance, Corrective Action Plan, Change Request
  - Timeframe to Remediate
    - Request through Variance extension of timeframe to remediate





## **Change Request Process**

- Variance
- Change Request
  - Submitted for only after Final Report
  - Subject to the Department's Review & Approval
  - Provide substantial evidence/documentation supporting the reason for change
  - Factors & Considerations
  - Changes will be submitted through the Registry
    - Specialist will review
    - Final recommendation sent to Director and/or Office of General Counsel for Approval/Denial
    - Notice sent to Primary Contact by email/registry



### Department prior Approval Required – Business Process Change Request 19 CSR 30-095.040 (4) (C) 1- 5

- Ownership changes, ten percent or more
- Material deviation to proposed/current physical design
- Location
- Combining licensed facilities (same or different ownership) to a single location
- Construction of a Warehouse
- Transfer to Entity not owned by same entities to which licensed (After 1/1/2021)
- \$2,000 Fee Per Change Request

Do you wish to remit an annual payment? Does this update application assign, sell, lease, sublicense, or otherwise transfer its license to any		No No
other entity and/or make changes to ten percent (10%) or more of the ownership interests of the facility?	0	No No
Does this update application involve a material deviation from the proposed or current physical design of the facility?	0	No No
Does this update application involve a change in the facility's location?	0	No No
Does this update application involve combining licensed facilities under the same ownership at a single location?	0	No No
Does this update application involve combining licensed facilities between two (2) or more entities with different ownership at a single location?	0	No No
Does this update application involve the construction of a warehouse sited at a location other than the approved location of the facility?	0	No No
Was your annual fee submitted outside of the online registry system?		No No



### Questions





# ENJOY YOUR LUNCH!

PLEASE RETURN TO THE MEETING ROOM BY 12:30



# NETWORKING OPPORTUNITY

### VISIT WITH FACILITY LICENSE AND COMPLIANCE STAFF AND MISSOURI STATE AGENCIES



# FACILITY COMPLIANCE

### **ANDREA BALKENBUSH** FACILITY LICENSE AND COMPLIANCE DIRECTOR

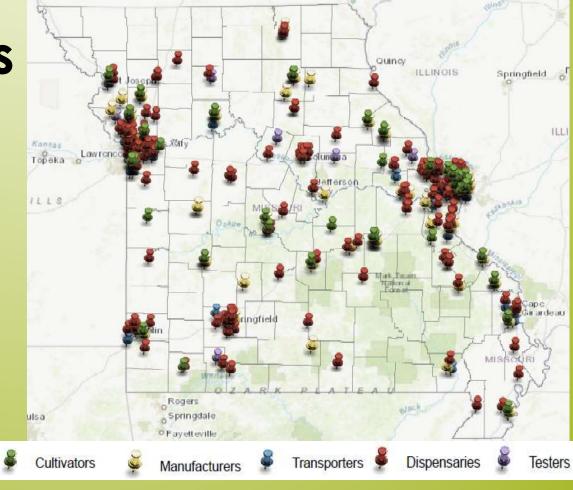


## **Licensed Facilities**

- Licensed facilities that will receive a commencement inspection
  - 10 Licensed Laboratory Testing Facilities
  - 60 Licensed Cultivation Facilities
  - 86 Licensed Infused Product Manufacturing Facilities
  - 192 Licensed Dispensary Facilities
  - 22 Licensed Transportation Facilities
  - 7 Licensed Seed to Sale Vendors

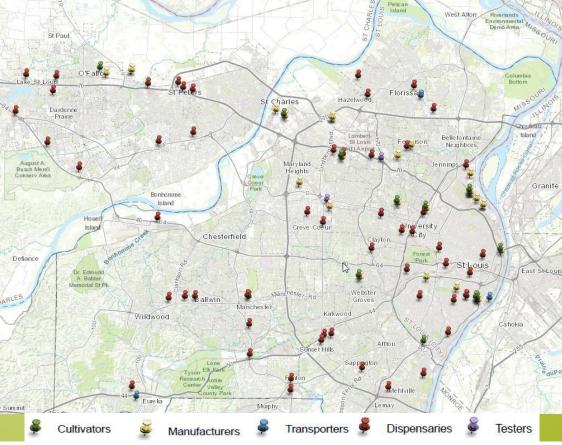


## **Facility Locations**





### Missouri Medical Marijuana Facilities St. Louis Area





### Missouri Medical Marijuana Facilities Kansas City Area





## **Important Notes for Licensees**

- The issuance of a license or certification does not authorize the facility to begin operations.
- A facility will be granted final approval to operate upon passing a commencement inspection.
- Facilities have up to 1 year to pass commencement.
- The facility will, at all times, comply with Article XIV and all other applicable laws and regulations.
- License Changes



## **Compliance Unit Core Functions**

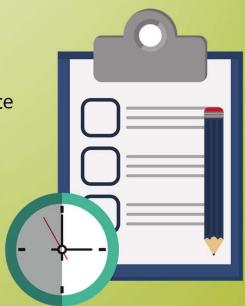
- Compliance Education
- Compliance Inquiries
- Inspections
  - Commencement
  - Annual
  - License renewal
  - Home Cultivation
- Complaint Investigations

- Compliance Visits
- Violations and Remediation Recommendations
- Seed to Sale Verification
- Track and Trace Monitoring
- Transportation Inspections
- Community Liaison



## **Inspection Types**

- Commencement inspections
- Annual inspections
  - At least annually after the issuance of the final approval to operate
- License renewal
- Complaint investigations





## **Compliance Visits**

- Provide education
- Answer facility questions
- Review operations in-between inspections
- Collaborate with facility staff and surrounding community





### **Commencement Prerequisites**

### **Considerations before requesting a Commencement** Inspection

- Is facility compliant with all local statutes, ordinances, rules, and regulations?
  - Documentation must be available for review
- Is facility compliant with all of the requirements and restrictions outlined in Article XIV and 19 CSR 30-95?
- Does facility meet the specifications presented with the initial application or as approved through a business update change request?
- Employee Training Conducted
- All fees paid



# **Facility Preparation**

- Once Commencement Inspection is requested, facility must work to:
  - Gain certification in the State's Track and Trace System (Metrc)
  - Secure Agent IDs for all facility employees, contractors and owners meeting the requirement
  - Prepare to answer questions
  - Prepare to provide documents for review



### **Commencement Process**

FL&CS will schedule Commencement Inspections when the following have been accomplished:

- Facility has received an Application Verification Review Complete Letter
- Verification of Welcome Meeting attendance
- All Business Update Requests that may impact a facility's Commencement Inspection have been approved by the department.





## **Commencement Process**

- Facility Request Commencement Inspection
- Pre-Commencement Inspection Checklist and Document Request
- Phone consultation
- Physical Commencement inspection
- Commencement Inspection Report
- Final approval to operate
- Or, address deficiencies





### **Commencement Inspection Request**

#### Step 1 – Request Commencement Inspection

- Request a Commencement Inspection, within a month of being ready for operations.
- FL&CS will verify the facility has met the prerequisites for a Commencement Inspection.
- FL&CS will send a Commencement Checklist and document request list for facility to fill out and return.

#### **To Request a Commencement Inspection**

- Send an official e-mail request to:
  - MMlicenses<u>@health.mo.gov</u>
- Must give 30-day notice





### **Commencement Inspection Checklist**

#### Step 2

 Facility will return checklist and all requested documents for review. This checklist may be used by the licensed facility for Pre-Commencement. This form shall not replace an official inspection conducted by the Facility License & Compliance Section and does not imply this facility has met all requirements as specified in 19 CSR 30-95.

License Number(s)	Facility Name	
Name of Owner	Name of Primary Contact or Person Responsible for the Commencement Inspection:	Expected Opening Date
Physical Address/City		Zip
Telephone	Email	<u>Fees Paid</u> □ Yes □ No
Type of Facility □ Cultivation □ Manufacturing □ Dispensary □ Testing □ Transportation		
$\Box$ Yes $\Box$ No $\Box$ NA	Certificate of Occupancy	
$\Box$ Yes $\Box$ No $\Box$ NA	Local fire and building permits	
$\Box$ Yes $\Box$ No $\Box$ NA	License displayed	
$\Box$ Yes $\Box$ No $\Box$ NA	One thousand feet from prohibited facilities	
$\Box$ Yes $\Box$ No $\Box$ NA	Facility agent identification cards for all employees	
$\Box$ Yes $\Box$ No $\Box$ NA	Attended DHSS Mandatory Welcome Meeting for facilities	
19 CSR 30-95025 Generally Applicable Provisions		
$\Box$ Yes $\Box$ No $\Box$ NA	Any variances for the facility?	
$\Box$ Yes $\Box$ No $\Box$ NA	The minimum standards met for licenses and certifications	
19 CSR 30-95.040(4) (C) Department Approval		



### **Commencement Inspection Review**

#### Step 3

- Once checklist and documents are received Compliance staff will:
  - Review the checklist items and flag any concerns.
  - Begin reviewing requested documents for compliance.
  - Review responses to Evaluation Criteria Questions for verification.

#### Examples of Requested Documents

- Standard Operating Procedures
- Employee Training Manuals and records
- Security Plans
- Operations plans
- Lab Testing Standards

#### **Documents must be Missouri Specific**



### Commencement Inspection Phone Consultation

#### Step 4

- FL&CS will schedule a conference call with facility to:
  - Review information provided
  - Ask questions
  - Determine if a physical Commencement Inspection should be scheduled or
  - Additional work is needed before scheduling a Commencement Inspection

### FL&CS will:

 Provide a Point of Contact for Compliance Unit





### **Physical Commencement Inspection**

#### Step 5

Physical Commencement
 Inspection of facility

**Examples** of Physical Facility Inspection

- Inspect all areas of the facility
- Demonstrate knowledge of working systems
- Complete review of security system
- Facility Licensee meets conditions under which it applied and was Licensed
- Seed to Sale/METRC requirements
- Agent IDs





### **Commencement Inspection Steps**

#### Step 6

 Once physical inspection is complete, a final report will be drafted documenting any deficiencies or violations.

#### Pass

 If pass, the facility will receive a Pass
 Commencement
 Inspection Letter and facility will be allowed to begin operating.



### Deficiency

- If deficiencies are found:
  - Facility will need to correct and show that the action has been corrected.
  - Request a follow-up Commencement Inspection





# **Final Approval to Operate**

- Once final approval to operate is issued, the facility will be authorized to begin cultivating, manufacturing, dispensing, testing or transporting medical marijuana
- No marijuana is allowed until a facility receives the Final Approval to Operate Letter





### Questions





# **AGENT IDs**

### **AMY MOORE**

**DEPUTY DIRECTOR AND COUNSEL** 



# **Agent ID Requirements**

- The fee for an Agent ID card is \$75
- Receive official letter of employment from a licensed facility
- Valid for three years
- Agent ID card holders must
  - Have their cards and a government issued photo ID accessible to them at all times while performing work in or on behalf of a facility
- All individuals who need an agent ID card per rule
  - Including contractors, should begin applying for their cards once the commencement inspection has been requested or scheduled
  - All individuals <u>must</u> have their Agent ID card at the time of the facility's commencement inspection



# **Agent ID Application**

- Applications and renewals must include:
  - Name, address and Social Security number of the applicant
  - Statement confirming applicant has submitted fingerprints within last 6 months for a state criminal background check through the MACHS portal
  - A copy of a written offer of employment from a licensed or certified facility
    - On facility letterhead
  - Government issued ID
  - Digital photo
  - All applicable fees
- Applications for Agent ID cards <u>must</u> be submitted through the Medical Marijuana Registry Portal
- The department has 14 days from the date of receipt to process Agent ID applications



# **Agent ID Waivers**

#### For Individuals Screened During Licensing

- Individuals who submitted fingerprints as part of a facility application will not be required to resubmit fingerprints as part of the facility Agent ID application.
- Such individuals have already been screened for purposes of licensing and need not be rescreened.
  - Applicants are instructed to check "Yes" to the related attestation in the facility agent application if they have submitted fingerprint as part of the facility licensing application process



# **Agent ID Waivers**

#### For All Other Individuals

- Waivers issued pursuant to 19 CSR 30-95.025(2)(A):
  - Until further notice, individuals applying for facility agent ID cards will only be eligible to request a Missouri open and closed records check and not a federal background check.
  - Individuals submitting fingerprints as part of a facility Agent ID card application must use the 8828 registration number and follow the instructions provided in the Agent ID Applicant Fingerprint Instruction Form



### Questions





# DISPENSARY-SPECIFIC INFORMATION OVERVIEW

### **ANDREA BALKENBUSH**

FACILITY LICENSE AND COMPLIANCE DIRECTOR

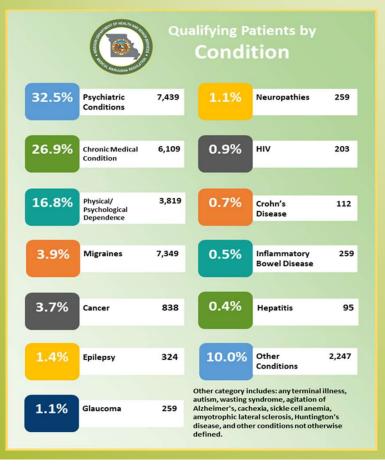


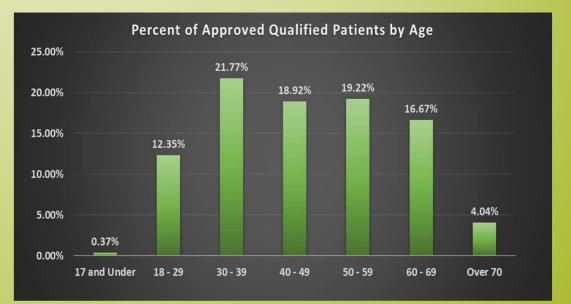
### Medical Marijuana-Dispensary Focus

- MO Patient Statistics
- Dispensary Expectations
- Dispensary Responsibilities to patient access and security



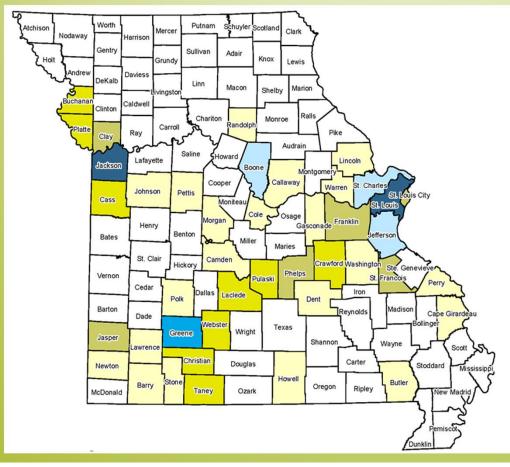
### **Qualifying Patients Statistics**

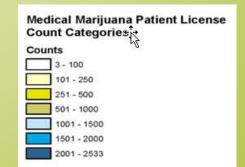






### **Patient Distribution**







## **Patient Screening**

- Only receive transaction orders from the qualifying patient or primary caregiver
- Verify qualifying patient or primary caregiver status and authorized purchase amounts in the statewide track and trace system at time of sale
  - If sale is for seeds, verify the qualifying patient's or primary caregiver's authorization to cultivate
  - Seeds must be acquired from a MO licensed cultivator



## **Patient Screening**

- Require individuals to display their qualifying patient or primary caregiver identification card and a government-issued photo ID at time of sale or delivery
  - If sale is for seeds, also require display of patient cultivation identification card
- Require up-front payment for delivery orders prior to the medical marijuana leaving the dispensary



## **Non-Emancipated Patients Under 18**

- Only parent/guardian may serve as primary caregiver
- Only the parent/guardian who holds a primary caregiver identification card is allowed to purchase or possess medical marijuana for a non-emancipated patient under 18



## **Controlled Entry**

- Single point of entry for general public, patients and primary caregivers
- Only qualifying patients, primary caregivers, and two additional persons to support the qualifying patient (if requested) may enter any areas beyond the facility's access point area
  - No medical marijuana allowed in screening area
- The number of qualifying patients and/or caregivers in areas where medical marijuana is accessible must be equal to the number of staff available to serve those individuals at that time



## **Controlled Entry**

- Entry to limited access areas should be controlled by:
  - Electronic card access systems, biometric identification systems or other equivalent means
  - Locking mechanisms for all external access doors that may be used in case of power failure.
- Access information shall be recorded, and all records of entry shall be maintained for at least 1 year



## Patient Safety, Security & Education

- Maintain confidentiality of patients and their information
  - Including the Health Insurance Portability and Accountability Act
- Dispensary facilities must make patient education materials available to all customers – these materials must include:
  - Local resources about addiction
  - Including the phone number for the Substance Abuse and Mental Health Services
     Administration's National Helpline
- Information about available medical marijuana strains available at the facility



## Patient Safety, Security & Education

- Information about the effectiveness of various methods, forms and routes of administering medical marijuana
- Potential risk and side effect information
  - Including the phone number for the closest poison control center
- Information about the prohibition on consuming medical marijuana in a public place
  - Including the definition of what constitutes a public place pursuant to 19 CSR 30-95
- Education for Dispensary Employees is Critical for patient security and safety



## **Physicians and Dispensaries**

 Physicians cannot meet with individuals on a dispensary's premises for the purpose of certifying them as a qualifying patient



# **Dispensaries and Transporting**

- Dispensary facilities can transport medical marijuana to:
  - Approved qualifying patients
  - Approved primary caregivers
  - Missouri Laboratory Testing facilities
  - Missouri Infused Product Manufacturing facilities
  - Other Missouri Dispensaries
- Dispensary must receive payment before the medical marijuana leaves the facility



# **Advertising Restrictions**

- No display of marijuana, marijuana paraphernalia or advertisements for these items that is visible to the general public from a public right-of-way
- Outdoor signage and indoor signage visible to the public must comply with local ordinances for signs or advertising



# **Advertising Restrictions**

- Do not display any text other than the facility's business or trade name, address, phone number and website
- Do not use images or visual representations of marijuana plants, products or paraphernalia, including representations that indicate the presence of these items, such as smoke
- Do not disburse medical marijuana as part of a promotional event



## Questions





# BREAK AND NETWORKING OPPORTUNITY

### VISIT WITH FACILITY LICENSE AND COMPLIANCE STAFF AND MISSOURI STATE AGENCIES



# STATE TRACK AND TRACE SYSTEM

#### **AMY MOORE**

#### **DAVID EAGLESON**

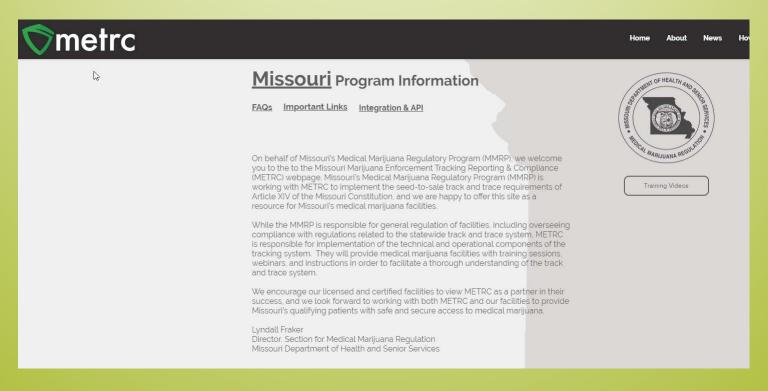
**METRC, PROGRAM MANAGEMENT DIRECTOR** 

#### **RILEY SISK**

**METRC, GOVERNMENT PROGRAM MANAGER** 



## Metrc





## Seed-to-Sale

#### If facilities decide to use a seed-to-sale integrator outside of Metrc:

- Facilities must utilize a Missouri approved Seed-to-Sale vendor
- A listing of Missouri Seed to Sale approvals and denials can be found at
- Information on the Seed to Sale application process can be found at

#### https://medicalmarijuana.mo.gov





## **Question and Answer Session**





## We look forward to working with you!

# Thank you!