MEDICAL MARIJUANA

Joe Pollock, Deputy Administrator
Division of Public and Behavioral Health
February 8, 2017
Background

• SB 374 passed in 2013
• DPBH tasked to build and launch MME program
  • Develop/adopt regulations by April 1, 2014
    – Prescribe initial and renewal application form
    – Set forth rules pertaining to safe and healthful MME operations
    – Establish fee structure to be revenue neutral over time
    – Set forth medical marijuana (MMJ) purchase limits
    – Protect identity of persons engaging in MME operations or use
    – Track physicians and MMJ recommendations
    – Establish agent card categories and agent training requirements
    – Maintain log of persons authorized to grow or produce MMJ, make available a variation log for law enforcement organizations (LEO)
• QuantumMark contract
  – Assist with implementation of the medical marijuana program (MMP)
  – Contract business objectives:
    • Staff infrastructure
    • Develop processes and procedures to support SB 374
    • Integrate licensing administrative functions
    • Implement customer centric program
    • Implement cost effective system which provides timely customer service
    • Implement all statutory provisions on time
    • Coordinate with Secretary of State, Taxation, DMV, LEO, local jurisdictions to meet mutual needs
Preparation (2 of 4)

• Analyze MMP Establishment staff requirements
  – 12 FTE
    • Program Manager 2 (grade 39)
    • Program Supervisor (grade 38)
    • 3 x Inspector 2 (grade 36)
    • 3 x Auditor 2 (grade 34)
    • Education and Information Officer (grade 35)
    • Program Officer 3 (grade 35)
    • 2 x Admin Assistant 3 (grade 27)
  – Develop job descriptions/performance standards
Preparation (3 of 4)

• Regulation development and adoption
  – Stakeholder meetings
  – Public workshop
  – Public hearing
• Develop MME application
• Define application scoring and ranking process
• Identify human resources required to conduct application scoring
  – Specify skill sets required
  – Assign organic state staff
  – Determine number of contractors required to evaluate the expected volume of applications
• Identify personnel training requirements and develop training materials to support application scoring
Preparation (4 of 4)

• Notice of intent to accept MME applications
  – 45 business days prior to accepting applications
    • Posted to website
    • Distributed via ListServ
    • Posted at other standard public locations

• Hired contractors to evaluate applications based on relevant skill sets (construction, financial, pharmaceutical, security, human resources/HR, etc.)
  – Initially hired 15 contractor evaluators
  – Hired an additional 6 contractors after application acceptance period

• Application evaluation training for evaluators
  – Two weeks intensive training on statutory and regulatory requirements, application scoring tools, and mock application evaluation exercises
    – MME 101, 201, 202, 203, 204

• Task organized evaluator teams based on skill set strengths
Application Processing

- Accepted application for 10 business days, Aug 5-18, 2014
- Each evaluator assigned to review either Identified Criteria or Non-Identified Criteria responses
- Teams scored applications using Evaluation Criteria Guidelines and scoring sheets developed by QuantumMark
  - Dispensary applications were ranked within the jurisdiction in which they applied
  - All cultivators, producers and labs with qualifying applications were awarded provisional registrations
  - Top ranking dispensaries were awarded provisional registrations up to the maximum amount allowed by law in each jurisdiction
- Monopoly analysis
- Requirements to obtain initial registration certificate
  - Satisfy all local jurisdiction building, inspection, permitting and business licensing requirements
  - Pay initial registration fee
  - Successfully undergo MMP Pre-Opening Inspection/Audit
- Initial registration fees
  - Collect them up front. We didn’t, but should have
Automation Systems
Medical Marijuana Portal

- Components

- MMP Portal

- Cardholder Registry
- Agent Registry
- DPBH Administration
- Cardholder Sales

- Hosted at EITS (virtual web server, physical database server)
- Security (SSL, secure logins, Microsoft Identity)
- Internet Access (User Accounts)
- Technical (.NET, SQL Server, C#, PHP)
Automation Systems
Cardholder Registry Web Site

• Features
  – Online registration
  – Online payments
  – Download bar-coded application
  – Upload completed documents
  – Download approval letter
  – Online application status check
  – DMV validation of cardholder data
  – Automated processing and mailing of registration card
  – Bar-code scanning of driver’s license data and documents
  – See statistics slide for counts

• Benefits
  – Faster application requests
  – Fast, easy submittal process
  – 24 hour approval for ‘good’ applications
  – Rapid application error resolution
  – Reduced errors on applications
  – Reduced issues with Dispensary patient verification and sales
  – Greatly improved turn around from initial application to receipt of registration card
Automation Systems
Agent Registry Web Site

• Features
  – Online accounts for designated agents
  – Online entry and submittal of agent initial applications and renewals.
  – Upload of all required application documents
  – Creation and printing of invoices
  – Management of all MME agents applications and data
  – Online payments in 2017
  – See statistics slide for agent processing numbers

• Benefits
  – Fast creation and submittal of agent applications
  – Easy creation of all required documents, pre-populated with agent information.
  – Easy access to application process through secure website
  – Online list of up-coming renewals
Automation Systems
DPBH Administration Web Site

• Features
  – Automated receipt of agent applications
  – Document review and application approval process online
  – Automated email notification to agents for incomplete applications
  – Secured access through online accounts
  – Local printing and mailing of agent registration cards
  – Manage/update MME demographic, contact and other information

• Benefits
  – Fast approval of agent applications, within one day for ‘good’ applications
  – Online availability and tracking of all agent and MME data to authorized users
  – Low cost for creation of registration cards
  – Infrastructure in place for automating MME application process
Automation Systems
Sales

• Features
  – Validation of active, approved cardholders against MMP database in real-time
  – Real-time sales data for ensuring patient purchase limits are not exceeded
  – Reciprocity sales from other states/countries
  – Conversion factor; 5 to 1 dry to THC infused products
  – See statistics slide for sales results

• Benefits
  – Instant validation that patient is approved for purchases
  – Prevention of any sale that exceeds limits
  – Prevention of sales to unauthorized persons
  – Tracking in real-time of all patient sales state-wide
Automation Systems
Leaf – MJ Freeway

• Features
  – State-wide system for collection of all MME inventory, test results, and sales data, implemented July 1, 2016
  – Fully hosted and managed by MJ Freeway
  – Full seed-to-sale inventory tracking and management system for medical marijuana
  – API interface from MMEs to Leaf to automate uploading of data
  – API interface from MMP to Leaf for MME and agent data
  – See RFP 3205 and MJ Freeway response for details

• Benefits
  – No cost to the State for this system
  – Little intervention required by State staff for managing system
  – State-wide visibility into all MME inventory and retail sales data for medical marijuana

• MMEs Integrated (166 Open)
  – 42 MMEs
  – 10 Labs set and able to enter data
  – Dec 31 target for open MMEs to be integrated
Automation Systems
Leaf – MJ Freeway (cont)

• **Key Functionality**
  – Tracks marijuana from initial acquisition (seed or clone) through cultivation, harvest, testing, manufacturing and dispensary activities
  – Maintains chain of custody for every plant, batch, lot, product throughout lifecycle
  – Provides detailed reporting and analytics on all aspects of the seed to sale lifecycle
  – Captures transport details and produces manifest for product movement
  – Captures lab testing details and maintains with plant or product throughout lifecycle
  – Unique ID for every plant, product and action ensures end to end traceability
  – Captures sales and tax information on retail sales

• **Major Updates Needed/In Process**
  – Labels, revised lab tests & parameters, updating reports for production run & additional data elements
  – Add flag indicating recreational sale
  – Add wholesale sales dollar and tax dollar tracking
Automation Systems
Other

- Law Enforcement Verification
  - PDF file, updated every two hours
  - Downloaded on demand by law enforcement
  - Lookup by patient/agent registration number or patient driver’s license

- Patient Verification
  - Bar-codes on IDs are scanned and populate initial cardholder record for initial applications; update patient information on renewals
  - Cardholder information is validated against DMV database through an automated interface
# Automation Systems

## Some Statistics

### State Sales

<table>
<thead>
<tr>
<th>Year</th>
<th>Grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>202,231</td>
</tr>
<tr>
<td>2016</td>
<td>3,364,644</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,566,816</strong></td>
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</table>

### Reciprocity Sales

<table>
<thead>
<tr>
<th>Year</th>
<th>Grams</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>54,694</td>
</tr>
<tr>
<td>2016</td>
<td>2,153,760</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>2,208,454</strong></td>
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</table>

### Agent Applications Received

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>3,161</td>
</tr>
<tr>
<td>2016</td>
<td>6,755</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9,916</strong></td>
</tr>
</tbody>
</table>

### Agent Applications Approved

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>3,071</td>
</tr>
<tr>
<td>2016</td>
<td>6,078</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9,149</strong></td>
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</tbody>
</table>

### Agent Cards Printed

<table>
<thead>
<tr>
<th>Year</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>2,721</td>
</tr>
<tr>
<td>2016</td>
<td>6,267</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>8,988</strong></td>
</tr>
</tbody>
</table>

### Patient Applications Approved 2016

<table>
<thead>
<tr>
<th>Before/After New System</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre New System</td>
<td>5,898</td>
</tr>
<tr>
<td>Post New System</td>
<td>18,638</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>24,536</strong></td>
</tr>
</tbody>
</table>
Operational Processes, Policies and Procedures (1 of 12)

• MME certification process (inspections, certificate printing)
  – MMP Inspector/Auditor team inspects MME after all local requirements have been met, ensures fees are paid, assembles certification file
  – Program Supervisor reviews and approves file, notifies Carson City staff
  – Registration certificate printed in Carson City, mailed to MME, with copies sent to Dept of Taxation, local jurisdiction, and Dept of Ag if the MME is a cultivator

• MME renewal process
  – MME submits electronic PDF renewal application, Inspector/Auditor team reviews packet, ensure fees are paid, and makes recommendation to Program Supervisor
  – Program Supervisor reviews and approves, notifies Carson City staff
  – Registration certificate printed in Carson City, mailed to MME, with a copy sent to local jurisdiction
Operational Processes, Policies and Procedures (2 of 12)

- **MME ownership transfer process**
  - MME submits Notice of Transfer of Interest form and supporting documentation
    - Fingerprint forms, updated org charts, state business license, legal buyout agreements, non-monopoly attestation
    - MMP Program Officer (PO) processes request, sends MME approval or denial letter, updates MME’s electronic file
    - 207 transfers completed to date, 11 pending. On average, ownership transfers take 6.5 hours to complete

- **MME location change process**
  - Allowed if proposed new location is in same local jurisdiction and approved at the local level
  - MME submits relocation request packet
    - Must contain evidence of local approval at a public hearing, proof the new location meets separation requirements from schools/community facilities
    - PO processes request, sends MME approval or denial letter, updates MME file
    - 90 location changes processed to date, 2 pending. On average, location changes take 6 hours to complete
Operational Processes, Policies and Procedures (3 of 12)

- MME production plan reviews
  - Required for all production facilities
  - Inspectors review building plans, ensure facility will meet food safety, sanitation requirements
  - Production plan approval letter is included in the MME’s certification file

- Background checks for MME agents
  - Agent card AA2 screens background reports, forwards questionable results to PO
  - PO reviews reports, determines if criminal history meets NRS 453A definition of “excluded felony offense,” directs follow up correspondence to applicants.
  - PO coordinates agent card denial or revocation actions as necessary, updates agent card portal
Operational Processes, Policies and Procedures (4 of 12)

• MME complaint investigation tracking
  – Program Supervisor oversees this function
  – Inspectors/auditors conduct investigation
  – If complaint substantiated, offending MME pays for the time and effort (T&E) to investigate

• MMP shared inspection scheduling calendar
  – AA3s maintain Outlook calendar based on Inspector input and other certification actions
  – Program Supervisor directs scheduling for routine (annual renewal) inspections
Operational Processes, Policies and Procedures (5 of 12)

• Logging and billing for T&E
  – Staff inputs billable hours weekly on T&E Master Event Log
  – Many T&E billable events occur in multiple parts over time
    • Initial registration certification
    • Ownership change requests
    • Complaint investigations
  – AA3 bills MMEs billed after the event is complete, maintains Billing Aging Report
Operational Processes, Policies and Procedures (6 of 12)

• Advertisement and logo approval process
  – NRS 453A requires Division approval of MME names, logos, advertisement and signage
  – MMP Education and Information Officer coordinates
  – Advertising Review Committee reviews all submissions, recommends approval or denial
  – Approval authority is MMP Manager
Operational Processes, Policies and Procedures (7 of 12)

- Independent Laboratory Advisory Committee (ILAC)
  - Advises the Division on matters related to lab testing of MMJ
  - MMP Education and Information Officer and AA3 coordinate public meeting requirements
  - Quarterly meeting
• Lab proficiency processes
  – Proficiency testing (PT) required
    • Within 6 months of initial registration and annually thereafter
    • Certified PT provider: Absolute Standards, Inc., conducts testing, sends results to the Division
  – “Round Robin” testing
    • Test for results consistency across all MME labs
    • Department of Agriculture facilitates, sends results to the Division
Operational Processes, Policies and Procedures (9 of 12)

- Tracking lab test results and follow up actions
  - Labs provide results to the program, results reviewed and e-filed
  - “Fail” results forwarded to Bureau Chief, Program Manager, Program Supervisor for decision
    - Retest
    - Send for extraction
    - Destruction
Operational Processes, Policies and Procedures (10 of 12)

• Published MMP policies
  – MME001 Location Change Requests
  – MME002 Advertising Guidelines for MMEs
  – MME003 Registration Certificate Revocation
  – MME004 Facilities Changes
  – MME005 Heavy Metals Testing Standards
  – MME006 Invoicing for Time and Effort for MMEs
  – MME007 Applicants Reviewing the Score of Their (MME) Application
  – MME008 Assigned Inspectors and Auditors for MMEs
  – MME009 List of Acceptable Pest Management Materials for Medical Marijuana Cultivation
Operational Processes, Policies and Procedures (11 of 12)

- Published MMP policies (cont.)
  - MME010 Ownership Change for MMEs
  - MME017 Combined and Separate Operations of Singularly Owned, Co-located MMEs
  - MME018 Pesticides Use and Testing
  - MME019 Inspections and Audits
  - MME020 Proficiency Testing for Medical Marijuana Independent Laboratories
  - MME021 Cannabinoid and Terpenoid Testing
  - MME023 Reporting Laboratory Testing Results
  - MME024 Renewal of Provisional MME Registration Certificates
  - MME025 MME Production Facilities Demonstration of Knowledge
Operational Processes, Policies and Procedures (12 of 12)

• Published MMP policies (cont.)
  – MME026 Scheduling of MME Inspections
  – MME028 Out-of-Office Procedure
  – MME029 CHOW and Location Change Procedures
  – MME031 Turnaround Times
  – MME032 Procedures for Selling Medical Marijuana to Nonresident Patients

• External policies are published on the DPBH website:
  http://dpbh.nv.gov/Reg/MME/dta/Policies/Medical_Marijuana_Establishments_(MME)_-_Policies/
Types of Inspections

- Preliminary Walk-Through (1.5 hours)
  - Optional

- Pre-Opening Inspection (2.5 hours)
  - Required prior to receiving certificate

- Dispensary Opening Inspection (1 hour)
  - Required prior to dispensary permission to sell

- Routine Inspection (2 hours)
  - At least once per year, may increase due to perceived risk and complaints

- Follow up Inspection (1 hour)
  - Discretion of inspector/auditor

- Complaint investigation (1-20 hours: varies based on allegations)
  - As received
Inspector Main Functions

- Each inspector conducts approximately 10 inspections/investigations per week
- Identify deficiencies in SOPs
- Identify potential problems with flow of facility and equipment
- Review materials of floor, walls, and ceilings to ensure they are smooth and easily cleanable
- Ensure operator is knowledgeable and capable of producing safe products
- Building and equipment are constructed in manner to prevent pest and bacterial harborage conditions
- Building, equipment and flow of processes are designed to prevent contamination (bacterial, chemical or physical)
- Production equipment meets commercial grade standards (NSF, ETL) and has been approved
- Identify any behavioral and/or hygienic practices that may lead to contamination
Auditor Main Functions

- Each auditor conducts approximately 10 audits/investigations per week
- Ensure agents have access to and training in inventory control system and State Portal
- Compare physical inventory count to inventory control system
- Verify all agents, owners, officer and board members have agent cards as required
- Ensure building is secure to prevent diversion of product
- Ensure all security cameras have adequate coverage
- Review patient intake documentation
Post-Inspection Process

• Prepare and send SOD (1 hour)
• Review POC (1 hour)
• Prepare and send UPOC or APOC (30 minutes)
• Compile final file (1 hour)
  – Pre-Opening only
Complaint Investigations and Lab Fails

• Receive average of 11 complaints per month, 115 since January
  – Contact and work with other local authorities as needed
• Average 78 failed lab tests per month, 843 since January
  – Follow up with facility to ensure it is quarantined
  – MME may request to send to extraction, approval based on probability that extraction will destroy the pathogen
  – MME may request retest
  – Witness destruction
Complaint Investigations and Lab Fails

Medical Marijuana Program Complaint Investigations & Failed Lab Tests
Data through 11/28/16

Division of Public and Behavioral Health
## Current Open Establishments

<table>
<thead>
<tr>
<th>MME Type</th>
<th>*Number of MMEs Originally Issued Provisional Certificates</th>
<th>Revoked / Expired / Surrendered Certificates</th>
<th>Final Certificates Issued</th>
<th>Remaining Provisional Certificates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispensary</td>
<td>66</td>
<td>0</td>
<td>54</td>
<td>12</td>
</tr>
<tr>
<td>Cultivation</td>
<td>182</td>
<td>10</td>
<td>66</td>
<td>106</td>
</tr>
<tr>
<td>Production</td>
<td>118</td>
<td>5</td>
<td>36</td>
<td>77</td>
</tr>
<tr>
<td>Laboratory</td>
<td>17</td>
<td>4</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Totals</td>
<td>383</td>
<td>19</td>
<td>166</td>
<td>198</td>
</tr>
</tbody>
</table>

*372 provisional registration certificates issued on 11-3-2014, and an additional 11 provisional dispensary certificates issued during 2015 pursuant to SB 276.
Current Open Establishments

Month and Number of MME's Issued Final Certificate

Division of Public and Behavioral Health
Medical Marijuana Patient Registry Total Caseload

Total case load is Application Requests, Registrations Received, and Renewal Applications. This fiscal year through December 2016, we are averaging a total caseload of 3,459 per month.
Future of the MMP

• Need
  – Patients under the age of 21
  – Stigma of being a recreational user
  – Research
Future of the MMP

• Growth dependent on:
  – Ease of obtaining and maintaining a patient card
  – Price differential between recreational and medical marijuana
  – Operator commitment
Questions?
Thank you!

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