Marijuana Enforcement Division
Consumer Safety Presentation

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Analysis & Planning Section
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Colorado Licensed Commercial Market

- Two Industry Segments
  - Medical
  - Recreational

- State and Local Licensing
  - State Licensing
  - Local Licensing

- Enforcement Authority
  - Regulatory (Title 12)
  - Criminal (Title 12 & 18 offenses)

- License Types
  - Stores/Center
  - Cultivation
  - Infused Product Manufacturers
  - Testing Facilities
  - Operators
  - Transporters
  - Research & Development
  - Research & Development Cultivation

Accela
DENVER MARIJUANA MANAGEMENT SYMPOSIUM
MAXIMUS
BIOTRACKTHC®
As of October 1, 2017 there are 3,025 Licenses Approved across the State

<table>
<thead>
<tr>
<th>License Types</th>
<th>Medical Licenses</th>
<th>Retail Licenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers/Stores</td>
<td>509</td>
<td>501</td>
</tr>
<tr>
<td>Cultivations</td>
<td>763</td>
<td>700</td>
</tr>
<tr>
<td>Infused Product Manufacturers</td>
<td>255</td>
<td>271</td>
</tr>
<tr>
<td>Testing Facilities</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>1,540</strong></td>
<td><strong>1,485</strong></td>
</tr>
</tbody>
</table>
An MED Occupational License/Badge is required for anyone working within Colorado’s Marijuana Industry.

- As of October 1, 2017 there are 35,940 Active Occupational Licensees.
Regulations Protecting Public Safety

* Production Management/Limits
* Inventory Tracking Rules
* Waste removal
* Restrictions on Purchase Amounts
* Restrictions on Hours of Operation
* Restrictions on Where One Can Consume
* Restrictions on Edibles
* Video Surveillance Requirements of Entire Premises
Regulations Protecting Consumers

- Extensive Labeling
- Packaging Rules
- Edible Restrictions
- Mandatory Testing
- Inventory Tracking Requirements

- Advertising Rules
- Purchase Limits
- Restrictions on Where One Can Consume
- Restrictions on Hours of Operations
Labeling Requirements

• Marijuana and marijuana-infused product sold or transferred to a customer must be in a container that is labeled with (to include):
  • license number of cultivation manufacturer, and store or center
  • potency test results
  • warning statements
  • production batch numbers
  • ingredient list
  • serving sizes
  • date of production, etc.
Edible Regulations

- Edibles must be placed in Child Resistant containers
- Limit the serving size for retail edible products to 10 mg of THC and limit the total mg of THC in a single package to 100 mg.
- Requirements for physically demarking multiple-serving edible retail marijuana products to show individual serving sizes.
- Labeling that includes explicit serving size, number of servings for package, and total THC for package
- Further limit attractiveness to children: prohibition on word “candy” or “candies”, no pre-manufactured products, and nothing in shape of humans, animals, or fruit.
- Equivalency limits
- Highlighting the potency in a bright color.
Packaging Requirements

• A Marijuana licensed business must ensure all marijuana and marijuana-infused product is placed within a container prior to sale of a customer and must meet the following criteria:
  • Required to be placed within a child resistant package; or
  • Required to be in an opaque and re-sealable exit package that is child resistant.
Retail & Medical Testing

**Products**
- a) Flower (bud)/Trim
- b) Edibles
- c) Concentrates
- d) Non-Edible Product

**Types of tests**
- a) Potency
- b) Homogeneity
- c) Contaminants
- i. Microbials
- ii. Residual Contaminants
- iii. Mycotoxins
- iv. Pesticides
<table>
<thead>
<tr>
<th>Table 9: Retail Marijuana Potency and Homogeneity Testing* (The term “package” refers to a single test batch submitted to a Testing Facility)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flower and Shake/Trim Packages Tested (Potency)</strong></td>
</tr>
<tr>
<td>Jan</td>
</tr>
<tr>
<td>3,019</td>
</tr>
<tr>
<td><strong>Infused Edible Packages Tested (Potency)</strong></td>
</tr>
<tr>
<td>Jan</td>
</tr>
<tr>
<td>827</td>
</tr>
<tr>
<td><strong>Concentrate Packages Tested (Potency)</strong></td>
</tr>
<tr>
<td>Jan</td>
</tr>
<tr>
<td>3,211</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 10: Retail Marijuana Contaminant Testing* (The term “package” refers to a single test batch submitted to a Testing Facility)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Flower and Shake/Trim Packages Tested (Microbial Contaminants)</strong></td>
</tr>
<tr>
<td>Jan</td>
</tr>
<tr>
<td><strong>Infused Edible Packages Tested (Microbial Contaminants)</strong></td>
</tr>
<tr>
<td>Jan</td>
</tr>
<tr>
<td>595</td>
</tr>
<tr>
<td><strong>Concentrate Packages Tested (Residual Solvent Contaminants)</strong></td>
</tr>
<tr>
<td>Jan</td>
</tr>
<tr>
<td>2,050</td>
</tr>
</tbody>
</table>
Pesticides

• Governor’s Executive Order (11/2015)
• CDA sampling and referrals to MED
• MED action and Health and Safety Advisories
• CDPHE led MDL study
• Proposed Limits
• Mandatory testing
Every mature plant in a licensed cultivation MUST have an individual METRC™ RFID tag attached and entered into the tracking system.
Individually track over 1 million plants at any one time
RFID tags are required to be attached to marijuana packages during transport and once received, entered into the inventory of the facility receiving the package.
Metrc™ Allows us to track the history of a Marijuana Plant from seed to sale.
METRC Tracked Transfers  Over 1 million

**MARIJUANA ENFORCEMENT DIVISION**

**MARIJUANA TRANSPORTATION MANIFEST**

All sales transactions are to be completed prior to transportation of any Medical Marijuana. The receiving entity may reject product delivered, but amount delivered must be limited to amount agreed upon in prior sales transaction. If the person transporting Medical Marijuana has not yet received his or her occupational license number, put "Pending" in the appropriate field.

**Manifest #:** 00000000603  **Date Completed:** 02/17/2016

**License # of Originating Entity:** 401R-X0001

**Name of Originating Entity:** CO LOFTY ESTABLISHMENT, LLC

**Address of Originating Entity:** 455 Sherman Street, Suite 390, Denver, CO 80203

**Phone # of Originating Entity:**

**Phone # MED Can Call with Questions:** 877-566-6506

**DESTINATION:** CO LOFTY ESTABLISHMENT, LLC

**Stop Number on Route:** 1

**Address of Destination:** 455 Sherman Street, Suite 390, Denver, CO 80203

**Route to Be Traveled:** Direct.

**Item Description** | **Item Label** | **Weight/Quantity**
--- | --- | ---
Buds - Blue Dream | ABCDEF012345670000012487 | 100.0000

**PRODUCT REJECTION** (if only a portion of shipment is rejected, circle that portion above)

**Name of Person Receiving or Rejecting Product:**

I confirm that the contents of this shipment match weight records entered above, and I agree to take custody of those portions of this shipment not circled above. Those portions circled were returned to the individual delivering this shipment.

**Signature:**

**Date:**

**Signature of individual taking receipt of rejected portion of this shipment:**

**Name of Person Transporting:** Bubba

**Occupational License # of Person Transporting:** X00420

**Make, Model, License Plate #:** Ford F150 811-abc
MED Mission Statement

• Our mission is to promote public safety and reduce public harm by regulating the Colorado commercial marijuana industry through the consistent administration of laws and regulations and strategic integration of process management, functional expertise, and innovative problem-solving.
Thank You

• Kyle Lambert
• Kyle.lambert@state.co.us
Denver’s Regulation of Marijuana and Cannabidiol Products

OR

A 21st Century Consumer Protection Odyssey

Kara Lavaux, Danica Lee
10/19/17

Denver Marijuana Management Symposium
# Denver Environmental Health

**Empowering Denver’s communities to live better, longer**

## 5 Divisions
- Office of the Medical Examiner
- Denver Animal Protection
- Environmental Quality
- Community Health
- Public Health Inspections

## Public Health Inspections
- 2 Division Sections
  - Food Safety & Marijuana
  - Healthy Families Healthy Homes

Partner closely with Denver Public Health

## Establishments
- Food Service
- Child care facilities
- Residential health
- Noise
- Lead
- Body art establishments
- Pools
- Boarding homes
Hemp versus Marijuana

- Both are species of cannabis

**Hemp**
- Long history of industrial use
- More recent breeding for CBD/therapeutic use
- Low in THC (less than .3% by law)
- Legal to transport across state lines? Up for debate (and litigation)
- Recent breeding for high CBD strains

**Marijuana**
- Long history of psychoactive use
- High in THC (5-30%)
- Not legal to transport across state lines
- All derivatives must remain within state-licensed MJ system
- Selective breeding for high THC and CBD strains, others
**CO Cannabis Legal Summary**

- Both are classified as Schedule I drug under federal law

**Hemp**
- 2014 Farm Bill created allowances for state hemp pilot programs
- Ingestible ingredients must be derived from seed, stalk, or stem
- 2015: Colorado Dept of Ag started industrial hemp program
- July 2017: CDPHE allows any part of hemp plant to be used in food

**Marijuana**
- Medical use legalized in CO in 2000 via constitutional amendment
- Proliferation of storefronts in 2009-2010 after legal challenges to caregiver model
- Voters approved Amendment 64 legalizing rec MJ in 2014
- Licensed/regulated by MED
DEH Background with Legal Cannabis

• 2010: Food safety inspections of marijuana food businesses begin
• 2014: Twice annual inspections of all Denver marijuana infused product manufacturers and retailers begin; first Denver MJ recall
• 2015: Enforcement actions for pesticide contaminated MJ products begin, first Marijuana Management Symposium
• 2017: CBD product enforcement, Cannabis Sustainability Guide, Marijuana Health & Safety Hotline
Cannabis concentrate production processes

**Cultivation**
Hemp or marijuana plants grown, “trim” used for concentrates

**Extraction**
Oils extracted from raw plant material via solvent, most commonly supercritical CO2 and butane

**Refinement**
Winterization, distillation, other methods to refine and purify extraction

**Decarboxylation**
Decarboxylation heat step to activate THC or CBD (if not achieved during extraction or refinement)

**Final processing**
Addition of terpenes, cutting agents, etc. to achieve desired flavor and viscosity

**DENVER ENVIRONMENTAL HEALTH**
Hazards of concentrate production processes

- **Cultivation**: Heavy metals, pesticide, mold, mites
- **Extraction**: Solvent impurities depending on grade, residual solvents, pesticides
- **Refinement**: Process dependent
- **Decarboxylation**: Higher temperature needed to decarb CBD compared to THC – hazards not identified
- **Final processing**: Addition of ingredients that haven’t been evaluated for smoking/vaping risks
- **End Product**: Shelf stability concerns, *C. Botulinum* hazard for ingested products

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DENVER ENVIRONMENTAL HEALTH

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[PHAB logo]
Production Equipment
2014: First Denver Recall
Shelf Stability of Ingestible MJ Extracts

Plant derived oils for ingestion must be temperature controlled unless one of the following:

- Plant material is irradiated
- Extract is suspended in alcohol and homogenous
- Thermal critical limit met
- Low pH/water activity is barrier to bacterial growth
- Product is labeled for smoking only
- Scientific research demonstrating safety of another critical limit is provided and approved

Businesses can submit HACCP-type plan for review and shelf-stability approval
Special Concerns Associated with Cannabis Extractions, Concentrations, Infusions, and Infused Foods

The Public Health Inspections Division (PHI) of the Denver Department of Environmental Health is responsible for enforcing regulations that preserve the health of consumers in Denver. PHI enforces the Denver Rules and Regulations Governing Food Establishments to regulate all food/products which are commercially manufactured and/or sold in Denver and that are ingested via non-smoking oral consumption (i.e. eating, drinking). Please visit www.denvergov.org/phi for more information or to view the Regulations.

Commercial manufacturing of cannabis-infused products is an emerging industry, and regulation of this industry is a new area of regulation. There is no known published research that addresses how pathogens grow in cannabis extractions and their derivatives. Until such information is available, it is the responsibility of PHI to enforce existing food regulations to protect the health of consumers and to use existing research and food science to assess the risks of foods. Requirements may change as new information becomes available regarding the safety of cannabis extractions.

What are the public health concerns associated with cannabis extractions and infusions? The extraction process can be dangerous if not performed properly, and the final extract can be harmful to consume if the extraction is not performed properly. All extractions must be conducted using a closed loop system with an approved solvent, and in Denver the system must be permitted by the Fire Department. Refer to the State’s Marijuana Rules for further information about extraction requirements.

_Clostridium botulinum_ is a bacteria whose spores are present on plant material and in soil. Spores are present in many plant material extractions and can survive cooking/pasteurization temperatures. These spores can spontaneously germinate (grow into bacteria) given the right conditions/substrate. The bacteria can produce a powerful toxin which can cause severe illness or death.

What are the products of concern? Affected products include:
- cannabis extractions and concentrates intended for non-smoking oral consumption (i.e. eating, drinking)
- most infusions made from these extractions, such as infused oils, butters, honey, etc.
Decarb steps/C. bot destruction

-MJ plant material must be decarboxylated ("decarbed") through heating to transform THCA (acid form) to THC that has psychoactive effect

-Lucky for us, this decarb step also destroys C. bot spores

-Without decarb step, ingesting plant material and derivatives has no psychoactive effect
Pesticide Contamination
Pesticide Contamination

Pesticide tolerances

When Denver quarantined 100,000-plus marijuana plants this year for unapproved pesticide use, myclobutanil and imidacloprid were two of the top culprits. Below are the EPA allowable tolerance levels for those pesticides in some common foods, and the levels that The Denver Post found in independent testing of two Mahatma Concentrates cannabis products.

<table>
<thead>
<tr>
<th>Fruit or Product</th>
<th>EPA Tolerance</th>
<th>Denver Post Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apple</td>
<td>0.5 ppm</td>
<td>0.5 ppm</td>
</tr>
<tr>
<td>Beef</td>
<td>0.10 ppm</td>
<td>0.30 ppm</td>
</tr>
<tr>
<td>Egg</td>
<td>0.02 ppm</td>
<td>0.02 ppm</td>
</tr>
<tr>
<td>Grape</td>
<td>1 ppm</td>
<td>1 ppm</td>
</tr>
<tr>
<td>Hops</td>
<td>10 ppm</td>
<td>6 ppm</td>
</tr>
<tr>
<td>Milk</td>
<td>0.2 ppm</td>
<td>0.10 ppm</td>
</tr>
<tr>
<td>Mahatma Concentrates' Black Label marijuana extracts</td>
<td>23.83 ppm</td>
<td>35.98 ppm</td>
</tr>
<tr>
<td>Grapefruit</td>
<td>0.76 ppm</td>
<td>0.69 ppm</td>
</tr>
<tr>
<td>Diesel wax</td>
<td>0.69 ppm</td>
<td>0.69 ppm</td>
</tr>
</tbody>
</table>

*Source: Environmental Protection Agency; Gobi Analytical
Severiano Galván, The Denver Post

Figure 3. Distribution of observed levels as a function of compound and product type. Shown are boxplots for each compound indicating the mean (solid black line) and quartiles. Overlaid on each boxplot are individual data points colored by product type (see legend). 100 ppb is indicated as a hashed line. Note: the y axis is log scaled so each increment represents a 10x level than the previous increment.
Pesticide Contamination

Number of Different Pesticide Residues Found on Each Product by Recall

Median # of pesticide residues found on recalled product samples = 3

Medical vs Recreational Number of Products Recalled

<table>
<thead>
<tr>
<th>Product</th>
<th>Number of Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>247</td>
</tr>
<tr>
<td>Recreational</td>
<td>174</td>
</tr>
</tbody>
</table>

DENVER ENVIRONMENTAL HEALTH

CONNECT WITH US  311 | POCKETGOV | DENVERGOV.ORG | DENVER 8 TV
Hemp Products in Early 2017

- Growing popularity of CBD products
- Increasing use of hemp as CBD source
- Concerns voiced by some in industry about snake oil phenomenon
- Hemp-derived CBD products are NOT REGULATED by anybody
- Many products coming from California; CBD concentrates sourced from Europe, China
DEH Action in April 2017

- Administrative holds placed on consumable CBD products in Denver from unregulated sources
  - Products from 42 manufacturers held
- Based in part on info from federal agencies, DEH indicates no hemp or derivative allowed from outside CO
- Holds also affect MJ manufacturers adding hemp derived CBD to products
DEH Action in April 2017

DEH offers remote plan and SOP review if manufacturers provide:

- Manufacturer name/address
- SOPs
- Ingredient list/sources
- Product labels
- Quality control & validation procedures
- Facility plans/layout
State involvement

- July 2017: CDPHE accepts wholesale food facility registrations for CBD ingestible product manufacturers
- CDPHE allows hemp and derivatives from outside CO provided:
  - Hemp is grown under a regulated industrial hemp program
  - Standards for ingestion/consumption are applied
- DEH aligns with CDPHE allowance for hemp grown under an industrial hemp program with standards for consumption—even if outside CO
- Still no regulation or authority over smoking/vaping hemp-derived CBD products
Update on Requirements for Hemp-Derived CBD Products Sold in Denver

In April 2017, Denver's Department of Environmental Health (DEH) published guidance regarding cannabidiol (CBD) products manufactured or sold in Denver. At that time, DEH also restricted the sale of CBD products originating from unregulated sources due to consumer safety concerns. However, CBD manufacturers were still able to pursue approval to sell in Denver by submitting documentation demonstrating evidence of safe and standardized operations. The DEH guidance also indicated CBD products, including hemp, that originated from outside Colorado, were considered from an unapproved source due to their unregulated status and the federal restrictions on interstate transport.

In July, the Colorado Department of Public Health and Environment (CDPHE) announced they will now accept wholesale food manufacturing registration applications for edible CBD product manufacturers. Approved manufacturers will be regulated under the Colorado Wholesale Manufacturing Food Regulations. CDPHE also indicated that hemp sourced from outside of Colorado is considered from an approved source provided all utilized parts of the hemp plant originate from a cultivator operating under a regulated industrial hemp program which applies safe consumption criteria. Since CDPHE's announcement, DEH has followed the same standards set by CDPHE.

DEH is continuing to evaluate Colorado CBD product manufacturers who are located outside of Denver upon request for those businesses that have not yet been inspected and evaluated by CDPHE. These evaluations allow impacted businesses to get approval to sell products in Denver in advance of a CDPHE inspection.

Businesses interested in this DEH evaluation should refer to the information addressed in the April DEH guidance. In lieu of a DEH evaluation, Colorado manufacturers outside of Denver can submit a CDPHE inspection report of their operation to DEH for review, if available. To get approval from DEH to sell in Denver, this report must demonstrate no outstanding violations that may contribute to significant consumer safety hazards.

Manufacturers of consumable CBD products outside of Colorado must show evidence of inspection or oversight by a regulatory health authority, such as a local or state health department or other regulatory authority, to proceed with sales in Denver. These products can be approved for sale in Denver provided there are no outstanding violations identified by the applicable health authority that may contribute to significant consumer safety hazards.

Questions? Contact the Public Health Inspections Division at phicommnts@denvergov.org.

As Denver’s nationally-accredited local public health agency, the Department of Environmental Health (DEH) is dedicated to advancing Denver’s environmental and public health goals. The divisions of DEH are: Animal Protection, Community Health, Environmental Quality, Office of the Medical Examiner, and Public Health Inspections.

For more information about DEH, visit www.denvergov.org/EnvironmentalHealth or follow us on Twitter: @DenverDEH.
Emerging issue – hemp and MJ
Concerns with ingredients added to smoking/vaping concentrates
Additives commonly include GRAS flavors, propylene glycol, glycerin, essential oils
Little research on smoking/vaping consumption
Cannabis-derived terpenes
DEH is enforcing against medical smoking/vaping MJ and CBD products additives if no safety evaluation or data
FDA’s regulation of Electronic Nicotine Delivery Systems (ENDS)
Launched in May 2017 by Rocky Mountain Poison & Drug Center in partnership with DEH/City of Denver

Intended for health surveillance, occupational safety hazard surveillance, resource for citizens and industry

Nearly half of calls within first few months related to CBD product questions

More than half of calls from callers outside of Denver and Colorado

MJ Health & Safety Hotline

Marijuana Health & Safety Line

Connecting you to trained medical and toxicology professionals

In partnership with the City and County of Denver, Denver Health’s Rocky Mountain Poison & Drug Center offers a free and confidential 24/7 phone line — to answer all your marijuana and cannabidiol (CBD) health and safety questions.

Medical providers and toxicology experts are here to answer marijuana health and safety questions 24/7 at 877-741-3777.

For immediate life-threatening emergencies, always call 911.

For Marijuana Consumers: Our caring staff of registered nurses and pharmacists are here to help, whether it’s explaining marijuana and CBD side effects, answering questions about edibles, or for better understanding Tetrahydrocannabinol (THC) — we’re ready for your call.

For Marijuana Industry Professionals: Our trained staff can assist industry inspection officers with toxicology questions and consultations — in an ever-changing industry, rely on our medical safety team for questions about pesticides, toxins, contaminants, additives or other ingredients that may be used in or found in the cultivation of marijuana in Colorado.

We are here to help at 877-741-3777.

When to Call: For Health and Safety Advice

- If you’re wondering, “can you overdose on weed?”
- If you’ve had any strange reactions to marijuana
- Questions about cannabidiol (CBD) products
- If you’re concerned about using marijuana while taking prescription medication, or using other drugs
- If you’re a health care provider with questions about marijuana
- If you’re experiencing concerning medical symptoms from marijuana use
- If you have concerns about the marijuana product you’ve purchased (packaging, smell, taste, serving size)
- Questions about occupational safety hazards for marijuana industry workers as well as others
Join us in the Mile High City to share ideas and learn about Denver’s collaborative approach to marijuana management.

REGISTER NOW

OCTOBER 19 & 20, 2017 • EMBASSY SUITES DOWNTOWN
Questions?

Danica Lee, Director
Public Health Inspections Division
Denver Dept. of Environmental Health
Danica.lee@denvergov.org
720-865-5378