



Manufactured Medical Cannabis Proposed Regulations: Overview & Key Elements

California State Association of Counties
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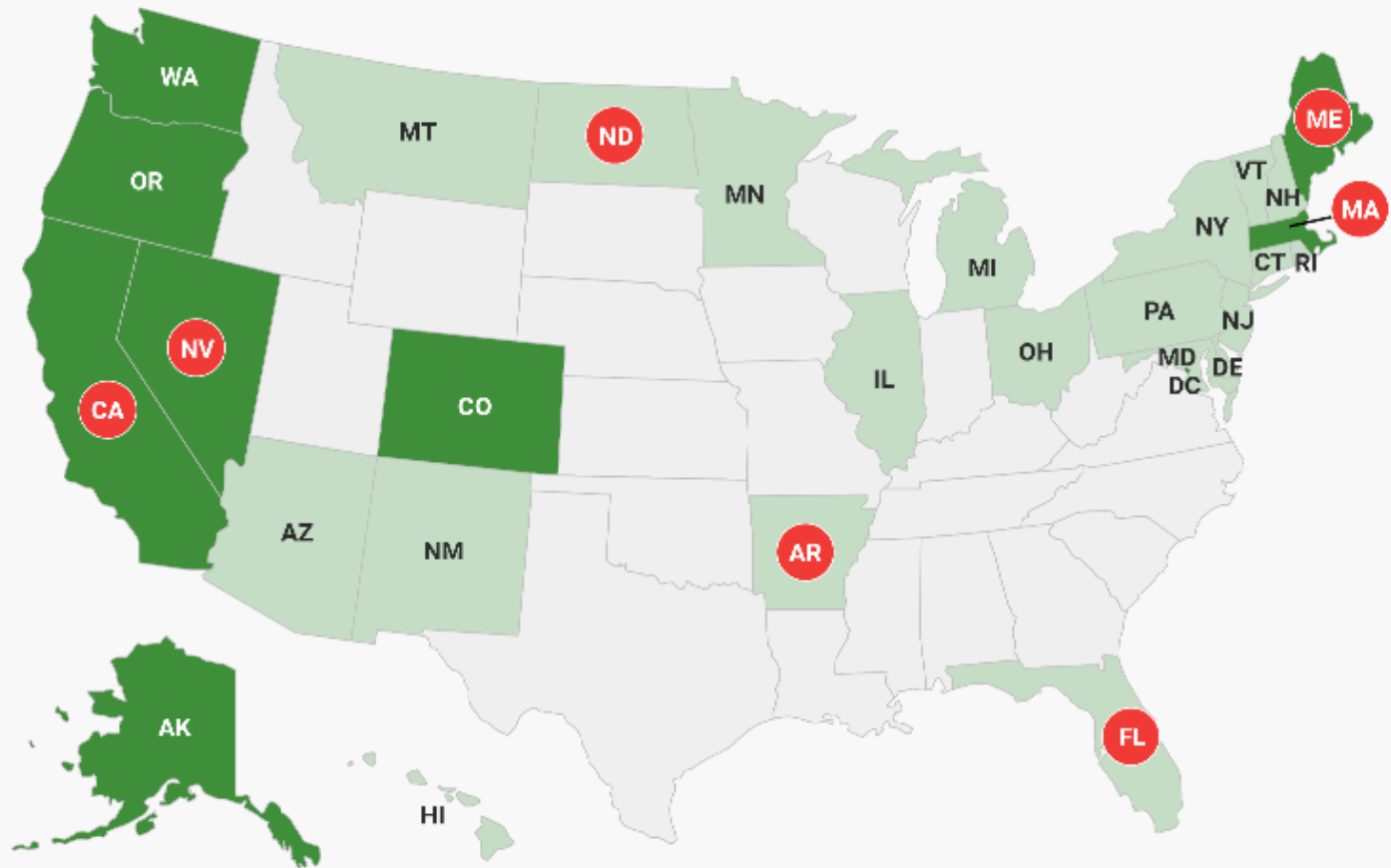
Outline



- Laws – How we got here
- Roles of state agencies – Licensing
- “Big Picture”
- Manufacturing Regulations – content
 - Licensing and Fees
 - Compliance and Standards
 - Packaging and Labeling
- Laboratory role
- Q&A

STATES WHERE MARIJUANA IS LEGALIZED

■ Legalized marijuana ■ Legalized medical marijuana ● Legislation passed Nov. 2016



SOURCES: Politico; Reuters

National Status

- 28 states & DC legalized medical use
- 8 states & DC legalized both medical and adult use

California



1996

- Proposition 215, Compassionate Use Act

2003

- Senate Bill 420, Medical Marijuana Program

2015/16

- Medical Cannabis Regulation & Safety Act

2016

- Adult Use of Marijuana Act (Prop. 64)

“...one regulatory structure of cannabis activities across California is needed.”

(<http://www.ebudget.ca.gov/FullBudgetSummary.pdf> , p.130)

(http://www.dof.ca.gov/Budget/Trailer_Bill_Language/documents/200CannabisRegulationDraft.pdf)

Licensing Authorities (MCRSA)



CDFA /
CalCannabis

- Cultivators,
- Track and Trace,
- Environmental Impact Report

CDPH /
OMCS

- Manufacturers

DCA /
BMCR -
BMC

- Transporters,
- Distributors,
- Testing Labs*,
- Dispensaries



* Prop 64 note: Testing labs to be licensed by CDPH (but TBL addresses)

Overarching Principles

Cannabis/cannabis infused products are neither food nor drug

Dual licensing: local control is at the core of the regulatory framework

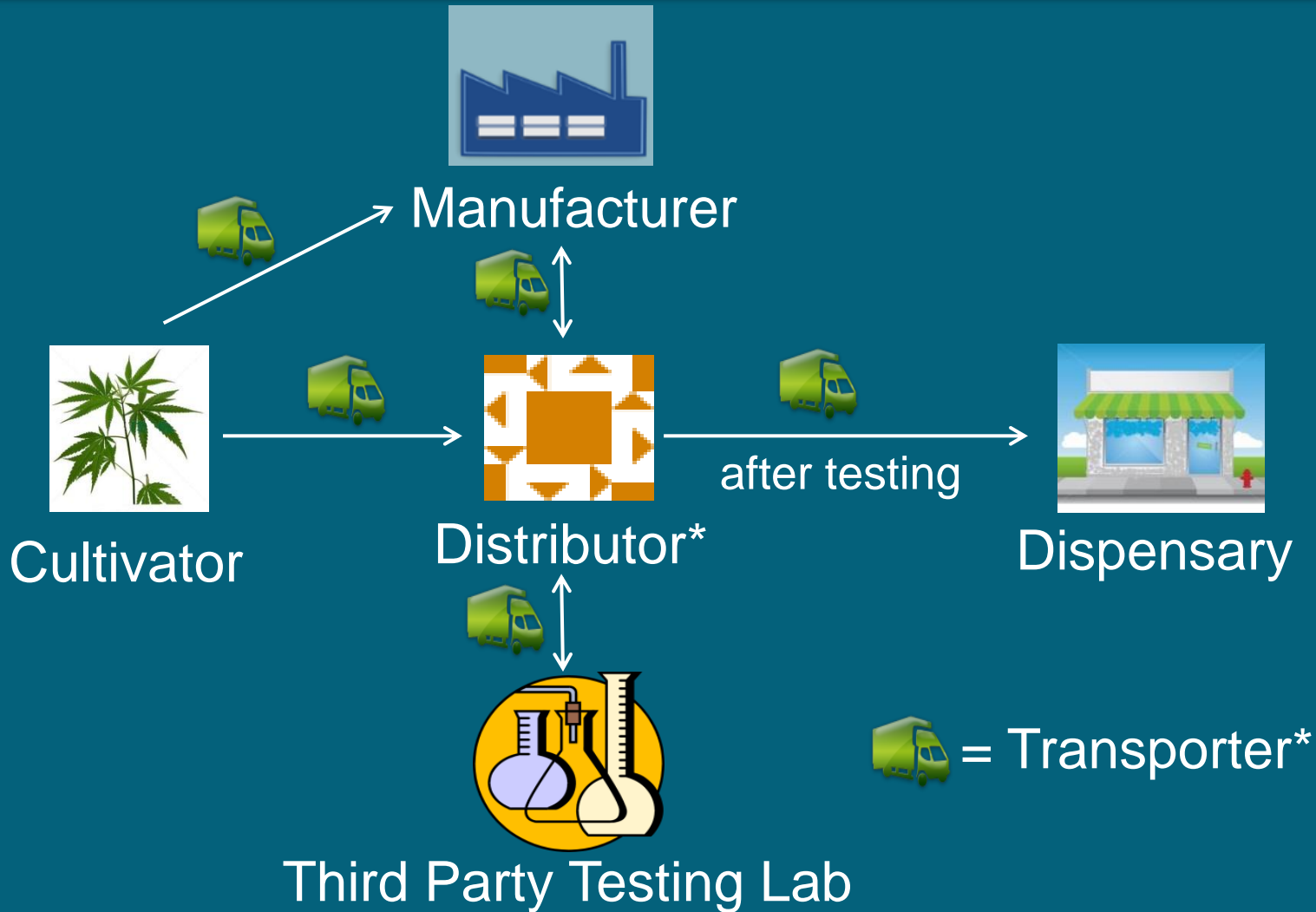
**Public Health
& Safety**

State responsible for inspection, enforcement, product safety, labeling and safe packaging, etc.

State sets minimum standards, locals can be stricter

Product Movement (MCRSA)

Between Licensees



* Prop 64 note: No transporter license; separate distributor not required; vertical integration allowed (except labs)

Scope

MC Products Example



Implementation Timeline



January 1, 2018

Staffing

Regulations

SRIA*

Database

Licensing

* Standardized Regulatory Impact Assessment

Goal: begin licensing as of January 1, 2018

Prop 64 note: Adult-use regulations will be generally similar and will utilize the emergency regulation process to meet this timeline

Approach and Resources



Guiding considerations

- Public health and consumer safety
- Enforceability
- Wide range of manufacturing operations and products

Office of
Manufactured
Cannabis
Safety
(OMCS)

Resources Used

- Other states regulations and Sherman Act
- CDPH Food and Drug Branch experiences & expertise
- Other State cannabis licensing authorities
- Stakeholder input (including manufacturers)

Regulations



Conducted Pre-Regulatory Stakeholder Meetings:

1. Redding - September 19, 2016
2. Sacramento - September 20, 2016
3. Santa Rosa - September 22, 2016
4. Oakland - September 26, 2016
5. Fresno - September 27, 2016
6. Los Angeles - October 4, 2016
7. San Diego - October 5, 2016
8. Santa Ana - October 18, 2016

Regulations (MCRSA)



Outline

- Definitions
- Licensing types and requirements
- Fee schedule
- Compliance
- Product standards*
- Packaging: not attractive to children, child resistant, and tamper proof*
- Labeling: primary and informational panel, warning statements and prohibitions*
- Standardized Regulatory Impact Assessment (SRIA)

* Prop 64 note: Some differences in Prop 64 (concentration, resealable, label, etc)

Manufacturing – Extractions

Example of Extraction Methods and Types of Solvents Used



Food based (e.g. oil, food grade glycerin, butter)



Supercritical fluid extraction (e.g., carbon dioxide)

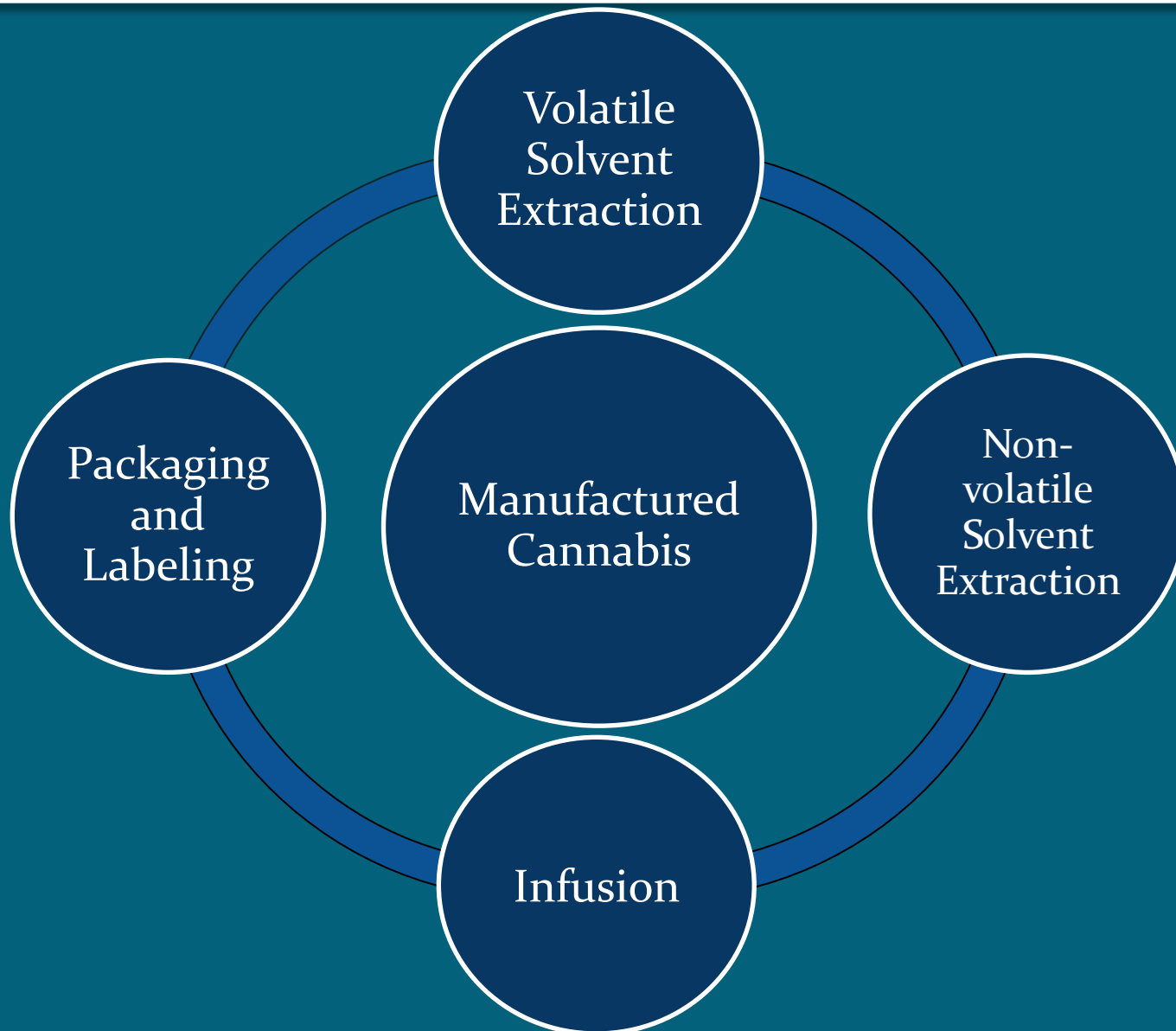


Uncompressed liquid solvents (e.g., ethanol, methanol, acetone, naphtha)



Compressed liquid hydrocarbons (e.g., butane)

Manufacturing – Types



Proposed License Types



- **Type 6** – Nonvolatile solvent extraction - water, food/oil, dry ice, mechanical, CO₂
- **Type 7** – Volatile solvent extractions - butane, hexane, propane, etc.
- **Type N** – Infusion only: purchase concentrate from another manufacturer and add it to their own products
- **Type P** – Packaging and labeling only: package and label other manufacturer's products

Proposed Fees



- One-time Application Processing Fee - \$1,000
- Annual License Fees (scaled, based on business size)

| <u>Gross Revenue</u> | <u>License Fee</u> |
|-------------------------------------|--------------------|
| Tier I - up to \$100,000 | \$2,000 |
| Tier II - \$100,000 - \$500,000 | \$7,500 |
| Tier III - \$500,000 - \$2 million | \$15,000 |
| Tier IV - \$2 million - \$5 million | \$35,000 |
| Tier V - \$5 million and over | \$50,000 |

Compliance Requirements



- Security measures
- Sanitary conditions
- Equipment, utensil, and surface sterilization procedures
- Assessment of potential hazards and implementation of preventive controls (aka “HACCP”)
- Standard Operating Procedures
- Transportation procedures
- Employee training record
- Inventory control, and record keeping
- Recall, and destruction / disposal procedures

Product Standards



- All components / ingredients of an edible product must be approved for use in food
- Cannabis product cannot be infused with nicotine, added caffeine, or alcohol
- Cannot make / infuse potentially hazardous foods (non shelf stable products) that are a higher risk of causing foodborne illness
- Cannabinoids must be uniformly distributed in the product
- Product must be free of contaminants

Packaging



Key Packaging Elements

- Not attractive to children
- Child-resistant
- Tamper-proof
- Opaque for edible products
- Resealable, if the package contains more than one serving
- All manufactured products to be packaged in their final form prior to release to a distributor

Labeling

“Primary panel”

- Total cannabinoid content per serving
- Total cannabinoid content per container / package
- Terpenes, if claimed
- “Cannabis-infused”
- Universal symbol



The information must be printed in no less than 6 point font size (1/12th of an inch)

NOTE: No claims of health or other physical benefits

Labeling



“Informational panel”

- Mandated warning statements
- Ingredient list, including potential allergens
- Edibles: sodium, sugar, carbohydrates, and total fat per serving.
- Solvents used
- Serving size, and number of serving per container
- Instructions for use
- Expiration or use by date

The information must be printed in no less than 6 point font size (1/12th of an inch).

Rulemaking Timeline



Proposed regulations for medical cannabis products:

- April 28, 2017 – OAL notification for 45-day public comment period
- June 13, 2017 – 45-day comment period ends
- Two 15 day comment periods, if needed
- January 1, 2018 – begin issuing licenses

Prop 64 (AUMA) and Trailer Bill proposed regulations:

- August/September – Emergency Regulations
- January 1, 2018 – begin issuing licenses

What to Comment on?



Rulemaking package contains multiple documents:

- The most useful comments are directed at the proposed regulatory text with the intent to improve the regulations
 - Include the section in the regulation text that you wish to comment on;
 - Have a written recommendation on what to change to the text; and
 - Explain your reasoning as to why change would benefit the manufacturing of cannabis, and public health & safety

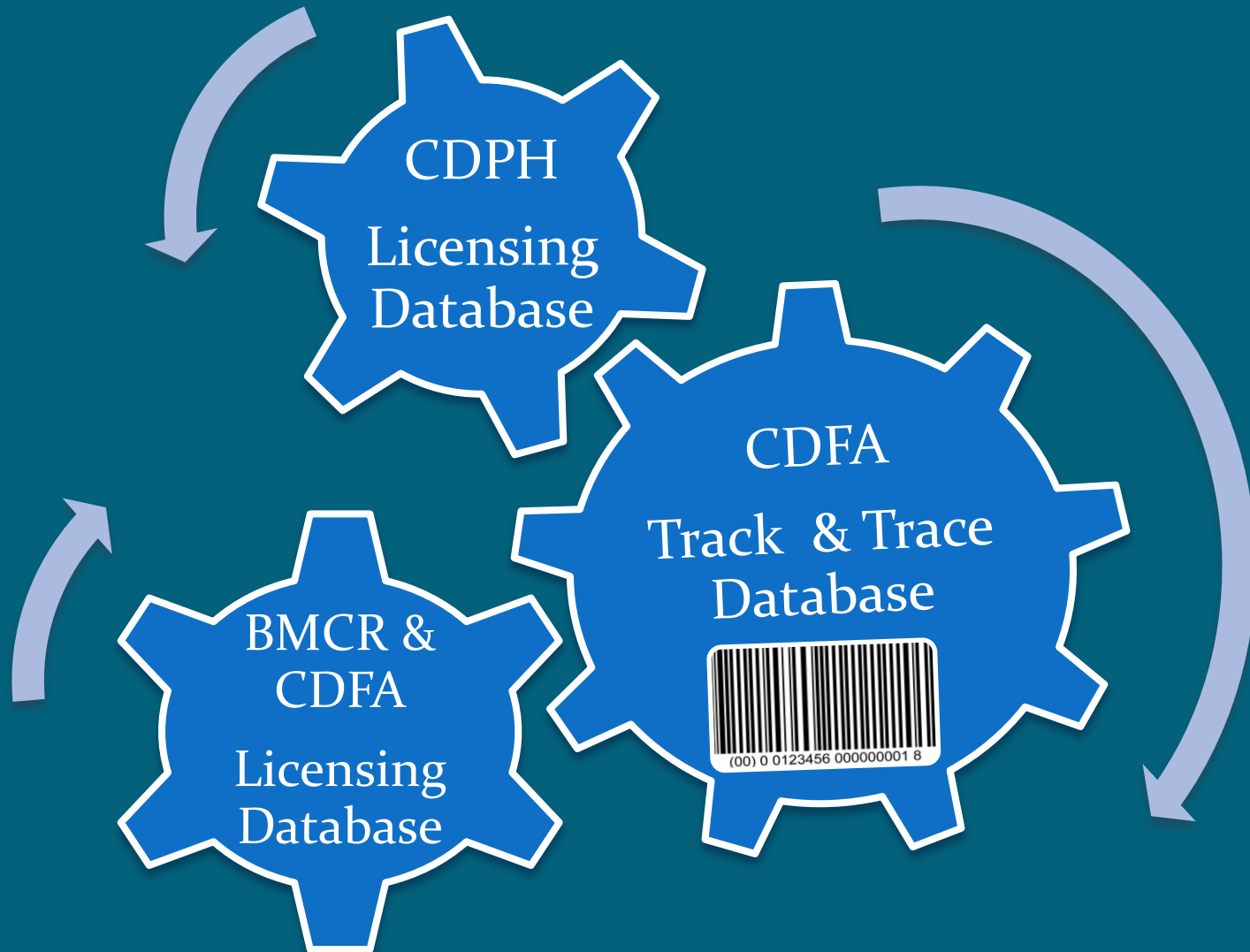
How to Comment?



Multiple ways to comment on proposed regulations:

- By mail: 1415 L Street, Suite 500, Sacramento, CA 95814
- By Fax: 916-440-5747
- By Email: regulations@cdph.ca.gov
- At a Public Hearing – verbally or in writing:
 - June 8, 2017, 10 a.m. – 1:00 p.m. At 50 D Street, Room 410A/410B, Santa Rosa, CA
 - June 13, 2017, 10:00 a.m. – 1:00 p.m. at 1350 Front Street, Auditorium, San Diego, CA
- *No comments over the phone!*

IT Solutions



Lab Testing Support

CDPH's Laboratory
Campus,
Richmond, CA



Key roles of CDPH cannabis laboratory:

1. Assist DCA to develop regulations for third party testing labs
Standards, methods, sampling, QC, staff, training, records, etc.
2. Compliance lab role in support of OMCS
Inspections, field samples, enforcement, etc.

Information



California Cannabis Portal:

<https://cannabis.ca.gov/>

OMCS webpage: www.cdph.ca.gov/omcs

Email: omcs@cdph.ca.gov

List Serve: LISTSERV@MAILLIST.DHS.CA.GOV

OMCS Chief: Asif Maan, Ph.D.



Thank You

Questions?