

## **Meeting Notes**

### **RULES ADVISORY COMMITTEE**

#### **Relating to Passage of HB 2546 Packaging and Labeling Standards for Inhalant Delivery Systems**

September 11, 2015 1:00 pm – 2:30 pm  
Portland State Office Building (PSOB), Room 1D

**Attendees:** Karen Girard (Oregon Health Authority), Heather Gramp (Oregon Health Authority), Bruce Gutelius (Oregon Health Authority), Sara Hartstein (Benton County Public Health), Kim La Croix (Oregon Health Authority), Letitia Mack (Oregon Health Authority), Susan Miles (Oregon Health Authority), Shawn Miller (NW Grocery Association/Miller & Associates) Matt Minahan (NW Vapor Association), Carrie Nyssen (American Lung Association of the Mt. Pacific), Shannon O’Fallon (Department of Justice), Tanya Phillips (Jackson County Public Health), Penny Pritchard (Deschutes County Public Health), Luis Rodriguez (American Cancer Society Action Network), Sandra Rood (Oregon Pediatric Society), Jesse Sweet (Oregon Liquor Control Commission), Becky Wright (Multnomah County Public Health).

#### **Welcome and Overview of Rulemaking Process**

- The meeting was convened by Heather Gramp at 1:03 p.m. with a welcome, information about call-in, meeting recording and logistics.
- The purpose of the Rules Advisory Committee (RAC) meeting was shared, specifically, to address rulemaking for the passage of HB 2546.
  - This RAC will address the provisions of HB 2546 related to child-resistant packaging, packaging not attractive to minors, and labeling requirements.
- The role of the RAC was described.
  - Committee members were selected to provide expertise and advice in rule making. OHA staff in attendance also have content expertise.
  - Observers are welcome to attend, but may not participate in the discussion. The RAC is not tasked with reaching consensus; individual advice is taken, and OHA will write rules that best reflect the statute.
  - RAC timeline: At least one more meeting of the RAC will be scheduled in order to review draft rules.
  - Final rules will be in effect July 1, 2016.

#### **Review Agenda and Meeting Plan**

- Heather Gramp recapped the previous RAC meeting held on August 26. Notes were sent to committee members and are available online: <http://www.healthoregon.org/morefreshair>. Heather Gramp reviewed the agenda for

the current meeting, indicating that today's RAC meeting will cover child-resistant packaging and packaging not attractive to minors.

### **Discuss Areas for Rule Development**

- Packaging Requirements for Inhalant Delivery Systems: Evidence has been reviewed related to packaging and labeling in regards to tobacco control for deterring youth access. Due to differences between the science on Inhalant Delivery Systems (IDS) and tobacco products, the proposed rules will not have the same level of warning as tobacco.

### **Referring to handout "definitions"**

- There are two sets: rules currently in effect and draft rules
  - Current rules regarding the Medical Marijuana Dispensary Program (MMDP) have definitions that pertain to packaging not attractive to minors, and can be applied to IDS as well.
- Kim La Croix shared a handout of proposed definitions

### **Committee Comments/Questions**

- There was general agreement on the definitions.
  - There was a clarification that these packaging rules apply only to IDS, not tobacco.
  - There were concerns stated about preventing all "cartoons," given that some logos could be considered "cartoons."
  - OLCC shared that they removed bright colors from their draft "attractive to minors" definition.
- Kim La Croix noted the definition of "cartoon" is in the draft OLCC rules and is from Tobacco Master Settlement Agreement and clearly defines what a cartoon is.

### **Committee Questions/Comments**

- There was discussion regarding cartoons. Most RAC members felt cartoons should be prohibited. It was noted that there was a similar issue in regards to Joe Camel. The only reason to have a cartoon logo would be to make a product attractive to minors.
  - There was discussion about the home and retail environment. Even if a minor cannot enter a location where IDS is sold, the package still needs to not be attractive to minors in the home environment.
  - The issue regarding defining bright colors was discussed. Oregon Health Authority's (OHA) MMDP current rules include bright color restrictions, and there haven't been enforcement issues; but it may not be uniformly applied. OHA's rules have been in effect for 18 months without a legal challenge.
- Heather closed the conversation on packaging "not attractive to minors" at this time, but it will be continued at the next meeting with some specific rule language to respond to.

## Labeling Requirements for Inhalant Delivery Systems: OAR 415-0060-0060

- Reviewed applicability and definition of IDS
- Discussion will encompass:
  - What will be prohibited from labels
  - What will be required on labels:
    - General content and design
    - Warning label content and design
- Prohibited Content proposals presented for discussion included:
  - Claims that don't meet the FDA Significant Scientific Agreement Standard; some possible perimeters proposed:
    - IDS aids in cessation of tobacco or other nicotine products
    - IDS is safer, healthier, or less risky than tobacco
    - IDS has health benefits (i.e., weight loss, relaxation)
    - IDS has curative or therapeutic effects
  - Anything otherwise prohibited on the package by rule (i.e., cartoons)

### Committee Questions/Comments:

- There were questions from the committee regarding updating rules and enforcement of labeling. Rules can be updated if needed when the science changes. At this time, the state is proposing to use the FDA standard of Significant Scientific Agreement (SSA). HB 2546 states that rules must align with FDA rules at a minimum.
- Required label content proposals presented for discussion included:
  - Business or trade name and address
  - Place of manufacture
  - Ingredients listed in descending order of predominance, by weight
  - Milligrams of nicotine in package
  - Concentration of nicotine (mg per ml) in package (if no nicotine, state 0 mg on label)
  - Warning label
  - Poison control number
- Labeling requirements will apply to the device, liquid, and components in keeping with how IDS is defined.

### Committee Questions/Comments:

- There was some discussion regarding need for business address and what would be considered the business address: the manufacturer, business address, or vape shop. The importance of having contact information is to be able to track down information in regards to poison control. It was suggested to include website information.

- OLCC shared a concern about how the rule regarding ingredients and nicotine content requirements would affect cannabis in regards to IDS, provided the ingredient is 100% marijuana flower and not edible. It was suggested that perhaps different rules can apply to different labels.
- Required label design proposals presented for discussion included:
  - Label must be printed in serif typeface, no smaller than 6 point font.
  - Type must be in smear proof ink.
  - Be in English, though it can also be in other languages.
  - May have more than one label affixed to the container (allows for warning label to be on additional label, not everything has to be on one).

Committee comments/questions:

- It was shared that the commonly used OHA standard for font requirement is Times New Roman. However, other fonts may be better for low literacy.
- There was a suggestion made that if the product is sold in multiple states, there could be a general label and an Oregon specific label added.
- Warning label content proposals presented for discussion included:
  - Not to be distributed or sold to minors
  - Keep out of reach of children

For products containing nicotine:

- Nicotine is toxic if inhaled or swallowed, or comes in to contact with skin or eyes.
- Nicotine's side effects (e.g. dizziness, rapid heart rate)
- Nicotine is addictive and habit-forming
- Not recommended for women who are pregnant or breastfeeding
- Not recommended for people with high blood pressure, heart disease, diabetes, or lung disease

Committee Questions/Comments:

- Some concern about listing multiple side effects was shared. It was noted that labeling that includes side effects is similar to medication warnings.
- It was noted that if a product did not contain nicotine, warning labels will just have content relating to distribution to minors and to keep out of reach of children.
- There was a suggestion to include on warning label to also keep out of reach of animals/pets.
- Warning label design proposals presented for discussion included:
  - Printed using (Times New Roman in keeping with OHA standard)
  - Font size no smaller than 6 point
  - Warning label must be located on front of the package

Committee comments / questions:

- There was discussion regarding font and literacy issues, but the general consensus was to keep font standards consistent.
- There were questions regarding what would be considered the “front of the package” and whether a warning label should be on the back or front. It was suggested to request input regarding warning label effectiveness from Oregon Poison Control.
- There was a discussion about serving size and nicotine content. There were questions regarding how a consumer would know how many servings were in a bottle of e-liquid. It was noted that nicotine levels are on some bottles currently and that serving size would vary depending on device used.
- It was suggested to use the National Institute of Standards and Technology (NIST) as a resource, to ensure labeling standards (e.g. uniform weights and measures).

### **Next Steps:**

There will be more research into current rules and standards and more input from content experts will be sought.

Once draft rules are written, they will be distributed in advance of the next meeting so members can have time to review.

There are still other aspects of the statute that have not yet been addressed, including enforcement and the statement of fiscal need and impact.

Committee members will be notified when next meeting date is set.

### **Process review and Final Questions**

Heather thanked the committee members for their participation and encouraged them to continue participating in this process with OHA. Heather adjourned the meeting at 2:28 p.m.