Meeting Notes

RULES ADVISORY COMMITTEE

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

November 3, 2015 1:30 pm – 3:30 pm
Portland State Office Building (PSOB), Room 1A

Attendees: Courtney Dresser (Oregon Medical Association), Sandy Giffin (Oregon Poison Control Center), 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), Jesse Sweet (Oregon Liquor Control Commission), Becky Wright (Multnomah County Public Health).

Welcome and Introductions

- The meeting was convened by Heather Gramp at 1:31 p.m. with a welcome, information about call-in and logistics.
- Rules Advisory Committee (RAC) members introduced themselves.

Review Progress to Date and Today's Agenda

- Heather Gramp provided a history of the previous RAC meetings.
    - Three meetings have been held, the last on September 11. Notes from the last meeting will be sent to committee members and are available online: http://www.healthoregon.org/morefreshair.
    - Heather provided an overview of the federal statutes, data sources, sample language and other contextual information that has been discussed to date and which has informed the draft rules that will be discussed today.
- Heather Gramp reviewed the agenda for the current meeting, indicating that today's RAC meeting will mostly cover the draft rules, including definitions packaging and labeling requirements for IDS, enforcement and penalties. Time permitting, the Committee will review the Statement of Need and Fiscal Impact.

Discussion of Draft Rules

Definitions

Kim La Croix led the committee through the draft definitions and source and intent of the definition, when applicable. See the draft rules sent on 10/28 for more details.

Question/Comments

- For "cartoon," there was a suggestion to remove section "D" since some of the language was redundant of sections a-c, and some language introduced the concept of a cartoon object, which could be problematic since it would prohibit a range of common images (e.g., a mountain).
- For "fillable IDS" and "liquid nicotine container," there was a suggestion to remove the term "consumer."
- For "packaged in a manner attractive to minors," there was a suggestion to make the distinction between the outer package and the product container clearer, including when these are one in the same.

Labeling Requirements for Liquid Nicotine and Pre-filled Inhalant Delivery Systems

Kim La Croix led the committee through the draft labeling requirements. The draft rules reflect the discussion from previous RAC meetings. See the draft rules sent on 10/28 for more details.

Questions/Comments

- There was a suggestion that section (1)(e)(C) under health warnings should specify individuals under 18 rather than generalizing minors because OLCC defines minors as under 21.
- There was a suggestion that containers that don't contain nicotine and those that do contain nicotine should have the same lab testing requirements. It was suggested that there should be a separate rule or definition for each.
- Percentage per volume was suggested for ingredient label, but it was noted that milliliters are needed by poison control, to determine an exposure level in the event of a poisoning. It was recommended that concentration (mg/mL), milliliters of liquid and milligrams of nicotine should all be listed.
- There was discussion regarding independent lab testing requirements:
    - It was noted that OLCC does not require alcohol to be independently tested but there is a required testing regimen for cannabis products.
    - Lab testing requirements and accreditation are very complex. It was suggested that if independent testing will be a requirement, then more explanation would be needed in the rules. It was suggested that OHA staff investigate industry standards to inform laboratory testing, or consider allowing independent testing protocols and documentation.

- It was noted that the lab testing requirement is about protection for consumers; ensuring that nicotine concentration is correct and important, especially when nicotine exposure results in calls to the Poison Center.

General Label Requirements and Exceptions

Heather Gramp led the committee through the remaining labeling requirements. The draft rules reflect the discussion from previous RAC meetings. See the draft rules sent on 10/28 for more details.

Questions/Comments

- There was discussion about specifying whether the rules apply to the outer package or inner package (i.e., container) or both. Some products (e.g., e-liquid bottle) are sold without an outer package and thus, the label must be on bottle. Some products are sold with an outer package (e.g. bottle in box).
- There was a comment that having labels required only on outer packages is insufficient.
- There was a suggestion that rules need to be made clearer to reflect that all "outer packages" and "liquid nicotine containers" need labels. The rules need a section stating where the label is required. There was a suggestion to break the rules up in order to make requirements for the different inhalant delivery system types and components more clear.
- There was concern that exemptions seem to state that zero nicotine containers don't need labels. It was noted that the rules will be clarified to show that *z*ero nicotine containers need a label but not a nicotine warning; however labels and warnings are not needed on fillable inhalant delivery systems (i.e, vape pens).

Packaging Requirements

- Heather Gramp led the committee through the packaging requirements. The draft rules reflect the discussion from previous RAC meetings. See the draft rules sent on 10/28 for more details.

Questions/Comments

- There was discussion about child resistant packaging being required on the device itself. It was noted that marijuana rules refer to the package that contains the item, not the inhalant delivery system itself.
    - If rules apply to the device itself being the package that requires child-resistant packaging, then that will need to be made clear in the rules.
    - Staff indicated that guidance from the Department of Justice on the draft rules, including this question in particular, will be provided.
- Oregon Poison Center noted that current data shows that kids are being poisoned by nicotine accessed through the fillable and pre-filled inhalant delivery systems (i.e, vape pens) more frequently than through the e-liquid bottles.

Enforcement, Violations and Penalties

Kim La Croix led the committee through the packaging requirements. The draft rules reflect the discussion from previous RAC meetings. See the draft rules sent on 10/28 for more details.

- Kim indicated that the enforcement language was mostly taken straight from language found in HB 2546.
- Violations and penalties will apply to sellers not in compliance with labeling and packaging requirements of HB 2546.
- Enforcement, violations and penalties related to sales to minors will be addressed in a separate rulemaking process in spring 2016.

Questions/Comments:

- It was suggested that rather than using the term "industry," the rules should specify wholesalers, retailers and/or distributors to ensure that is it clear what entities these rules apply to.
- There was a suggestion to clarify how the rules apply to distributors, especially those located in Oregon but distributing products in other states (e.g., Idaho). There was a question whether the rules apply to any inhalant delivery system if it is manufactured in Oregon, regardless if it is distributed elsewhere.
- There was discussion regarding providing a detailed schedule indicating the amount of first violation, second violation and so forth, and how fines are applied over those time period.
- There was concern noted that no mechanism currently exists for OHA to test for nicotine content.

Review of Statement of Need and Fiscal Impact

Heather Gramp polled the RAC to determine whether they would prefer to meet again inperson to discuss a next iteration of the draft rules, or simply make final comments on the rules once released. Since the committee wished to meet again, the review of the statement of need and fiscal impact was postponed to the next meeting.

Review of timeline and next steps

- OHA will follow-up on the feedback from the RAC and receive further feedback from the Department of Justice before releasing another draft of these rules.
- OHA will convene the RAC to discuss the draft rules and the statement of need and fiscal impact form, prior to January 1.
- Committee members will be notified when the 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 3:31 p.m.